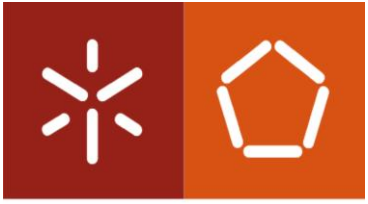

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Biofeedback system to improve the human-orthosis interaction

Dissertação de Mestrado

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STATEMENT OF INTEGRITY

I hereby declare having conducted this academic work with integrity. I confirm that I have not used plagiarism or any form of undue use of information or falsification of results along the process leading to its elaboration.

I further declare that I have fully acknowledged the Code of Ethical Conduct of the University of Minho.

RESUMO

A cada ano, 15 milhões de pessoas, mundialmente, sofrem um acidente vascular cerebral (AVC). Mais de 80 % dos sobreviventes apresentam incapacidades de marcha, limitando a sua independência motora e bem-estar. Estes pacientes podem recuperar a sua independência motora através do uso de ortóteses ativas. Adicionalmente os sistemas de *biofeedback* (BSs) podem ser usados como uma ferramenta complementar da reabilitação assistida por ortótese, informando os usuários, oportunamente e objetivamente, acerca do seu comportamento durante a execução de uma tarefa, e ensinando-os a melhorar a sua interação com a ortótese; assim, acelerando e aumentando a eficácia da recuperação. Não obstante, existem poucos BSs desenvolvidos para a reabilitação assistida por ortóteses, os quais não são vestíveis.

Esta dissertação tem como objetivo o desenvolvimento de um BS vestível, autónomo e modular para ser integrado na ortótese de tornozelo do sistema SmartOs, baseando-se numa visão centralizada no utilizador. O BS desenvolvido fornece estimulação sensorial, sonora e visual através de motores vibratórios, auscultadores e um díodo emissor de luz vermelha-verde-azul, respetivamente. O BS inclui um microcontrolador que gere a ativação dos estímulos de acordo com o torque de interação e trajetória de referência da ortótese do tornozelo. Os estímulos sensorial e sonoro foram escolhidos para ensinar o utilizador sobre: quando e como executar o contacto entre o pé, parético e não parético, e o solo; o sentido de rotação do tornozelo ao longo do ciclo da marcha; e a força muscular necessária ao longo do ciclo da marcha. O estímulo visual é usado para ajudar o terapeuta a seguir o desempenho dos pacientes ao longo da terapia, de forma que o terapeuta possa ajudá-los e motivá-los.

A partir da validação com sujeitos saudáveis, verificou-se que o BS aumentou significativamente o desempenho motor do utilizador durante a marcha com a ortótese. O sistema mostrou-se capaz de ensinar os utilizadores sobre a direção e magnitude da força muscular necessária ao longo do ciclo da marcha, melhorando a interação entre o humano e a ortótese. O trabalho futuro envolve a melhoria das estratégias que visam o contacto entre o pé e o solo e a validação do sistema com mais participantes e treinos mais longos.

PALAVRAS-CHAVE: AVC, BS, interação entre humano e ortótese, reabilitação da marcha assistida por ortóteses.

ABSTRACT

Every year, 15 million people worldwide suffer a stroke. More than 80 % of stroke survivors present gait disabilities, limiting their motor independence and well-being. The patients may regain their motor independence with active orthoses. Biofeedback systems (BSs) may be used as an orthotic rehabilitation's complementary tool to inform the user timely and objectively about their behaviour during gait. Thus, teaching the patients how to improve the human-orthosis interaction. Overall, this allows accelerating and increasing the effectiveness of the gait recovery. Nonetheless, there is a lack of BSs for orthotic gait rehabilitation, and no wearable solution is available.

This dissertation aims the development of a wearable, stand-alone and modular BS to be integrated into SmartOs-ankle orthosis, following a user-centered design. The developed BS provides sensory, sonorous, and visual stimulation through vibrotactile motors, headphones, and a Red-Green-Blue Light-Emitting Diode, respectively. The BS includes a microcontroller to manage the activation of the stimuli according to the interaction torque and the reference trajectory of the SmartOs-ankle orthosis. The sensory and sonorous stimuli were chosen for developing user-oriented strategies to teach the user, as follows. When and how to perform the paretic and non-paretic foot-floor contact (foot-floor contact biofeedback); the direction of ankle rotation along the gait cycle (joint motion biofeedback); and, the necessary muscular strength along with the gait cycle (user participation biofeedback). The visual stimulus is used to help the therapist to follow the performance of the patients during the therapy and, consequently, help and motivate them – therapist-oriented strategies.

From a validation with healthy subjects, the BS increased the user's motor performance significantly when walking with an orthosis. The system was able to teach the users about the direction of ankle rotation and the necessary muscular strength along with the gait cycle, improving the human-orthosis interaction. Future work towards enhancing the foot-floor contact strategies and extending the BS validation with a large group of participants and longer training period.

KEYWORDS: biofeedback system, human-orthosis interaction, orthotic gait rehabilitation, stroke.

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List of Acronyms

AGRF – Anterior Ground Reaction Force

AO – Active Orthosis

BiRD Lab – Biomedical Robotic Devices Laboratory

BS – Biofeedback System

CMEMS – Centre of MicroElectroMechanical Systems

ERM – Eccentric Rotating Mass

FEL – Feedback Error Learning

FSR – Force Sensitive Resistor

HO – Heel-Off

HS – Heel-Strike

PAFO – Power Ankle-Foot Orthosis

PID – Proportional Integral Derivative

RGB LED – Red-Green-Blue Light-Emitting Diode

RQ – Research Question

SmartOs – Smart Control of a Stand-alone Active Orthotic System

TO – Toe-Off

1. INTRODUCTION

This dissertation presents the work developed in the scope of the fifth year of the Integrated Master's in Biomedical Engineering, at the University of Minho, during the academic year of 2018-2019.

The academic year started with an Erasmus Placement traineeship in Marsi Bionics, Alcalá de Henares, Spain, that allowed to acquire in-depth knowledge about human biomechanics and its modelling. During this period, a mathematical model was developed to fit experimental kinematic and kinetic data from human lower limbs during sit-to-stand and stand-to-sit conditions. The experimental data were acquired from 14 healthy subjects using a complete gait laboratory. The statistical analysis of the acquired data can be found in the published paper "Kinematic and kinetic study of sit-to-stand and stand-to-sit movements towards a human-like skeletal model" in the 6th IEEE Portuguese Meeting on Bioengineering.

The remained period of the academic year was passed working in the Biomedical Robotic Devices Laboratory (BiRD Lab) included in the Centre of MicroElectroMechanical Systems (CMEMS) Research Centre, at University of Minho, Braga, Portugal. During this period, it was developed a wearable, stand-alone and modular biofeedback system (BS) inserted in the Smart Control of a Stand-alone Active Orthotic System (SmartOs). This system was developed to improve the human-orthosis interaction aiming the rehabilitation process acceleration. All the methods, results and conclusions are detailed in this document.

1.1 Motivation and Problem Statement

Every year, 15 million people worldwide suffer a stroke [1]. In the early 2000s, approximately 1.1 million Europeans suffered a stroke per year. It is estimated that by 2025, the number will increase to 1.5 million Europeans [2]. Moreover, over the last 20 years, more people are surviving stroke and, consequently, are being left with disabilities [3]. Due to this, stroke is the leading cause of long-term disability [4]. Muscle paralysis or loss of muscle strength, postural instability, abnormal gait pattern, and impaired functional motor ability are some post-stroke sequelae [5].

Gait is a fundamental activity of an independent and healthy daily life [6]. Its safe execution requires a coordinated activation of muscles and balance [7], which are usually affected after a stroke [8]. Gait abnormalities occur in more than 80% of stroke survivors [8]. Post-stroke patients perform excessive foot inversion, which reduces the propulsive force during the gait push-off phase [7]. The propulsive force is

responsible for accelerating the limb forward during the swing phase [9], resulting in a slower gait speed [10]. Additionally, the decreased weight loading in the paretic limb causes temporal asymmetry between the legs [11] and excessive loading in the nonparetic limb, which can lead to joint degradation [12]. Moreover, these gait abnormalities place stroke survivors at a high risk of falls [13]. According to the current situation, there is a need to focus on the improvement of strategies for post-stroke motor regain.

Stroke survivors may recover their motor function and regain their motor independence through neuroplasticity phenomenon [14]. Neuroplasticity is the change in neural pathways that allows the brain to rewire functions from damaged central pathways over to healthy and unused central pathways through task practice [14]. This phenomenon has been employed by means of physical and robotic therapies [15]. The physical therapy, as the conventional gait therapy, involves the execution of daily tasks with the guidance of a therapist [15]. On the other hand, the robotic therapy includes robotic devices that provide body-weight support, repetitive rehabilitation and guidance of the legs according to the users' needs [15]. Through the guidance of a therapist or robot, the user performs the walking task, activating the healthy and unused central pathways, which contributes to neuroplasticity [15].

The robotic assistive devices, such as exoskeletons and active orthoses, are increasingly being integrated into everyday clinical practice because they offer an intensive, user-oriented and repetitive gait training, allowing efficient long-term gait rehabilitation [15]. Contrarily to physical therapy, robotic therapy provides objective information about the user's motor condition and evolution of the user's performance through the embedded sensors in the robot. Moreover, it is less therapist-dependent because one therapist can adequately supervise multiple patients who train on different robotic devices [14]. There is evidence that the combination of robotic and physical therapies improves and accelerates the post-stroke gait recovery [15].

Current directions in gait rehabilitation aim for the integration of biofeedback-based therapy. It uses a biofeedback system (BS) that, as posited by Wolf, allows the patients to learn how to autonomously activate the unused pathways in the brain, contributing to neuroplasticity [16], [17]. BS is an electromechanical device that includes sensors and stimulators to measure the user's motor activity (e.g., kinematic, kinetic, spatiotemporal and/or physiological parameters) and to, timely, provide this motor information to the user through visual, sonorous and/or sensory stimulation, respectively [18]. As posited by Wolf, the provided stimulus activates unused or underused neural central pathways to execute motor instructions, contributing to improve the patient's motor function and to enhance motor relearning [16], [17].

The development of BSs at post-stroke gait rehabilitation significantly started in 2016 and there is an increase over recent years [18]. BSs are a promising tool to complement post-stroke physical therapy by providing timely information about the user's physiological functioning to both the patients and therapists [18], [19]. Otherwise, this information is too subtle to detect and too subjective to assess and manipulate by a therapist accurately [20]. There are promising results concerning the use of BSs to increase the post-stroke gait symmetry, weight bearing [21], [22] and propulsive force during push-off phase [23].

On the other hand, there is the possibility to apply BSs during robotic-based gait rehabilitation to improve the functional and biomechanical motor recovery. BSs can objectively evaluate the patient's movement and, according to this information, encourage the patients to autonomously improve the human-robot interaction and, consequently, their gait pattern [24]–[27]. Although the robotic assistive devices can guide the user's legs according to a healthy gait pattern, in the rehabilitation field, the goal is to teach the patients how to perform the healthy gait pattern autonomously [15]. Therefore, the BSs can teach, objectively and timely, the patients to follow the orthosis's pattern; thus, accelerating and increasing the effectiveness of the recovery [24]–[27]. Furthermore, if the therapists can easily and accurately assess the user's motor performance during closed-loop gait training, they may adjust the users' movement accordingly and encourage their involvement, favouring gait recovery [24]–[27].

Nonetheless, there is a lack of these systems in the orthotic rehabilitation field, and there is yet no wearable technological solution available. In this manner, there is a need to focus on the development of a wearable BSs for post-stroke orthotic gait rehabilitation, aiming the acceleration of the recovery process through the human-orthosis interaction improvement.

1.2 Goals

The ultimate goal of this dissertation is the design, development, and validation of wearable, stand-alone, and modular BS to be used as promising complementary tool of the SmartOs, a Power Ankle-Foot Orthosis (PAFO), aiming the acceleration of the gait rehabilitation process through the improvement of the human-orthosis interaction and cooperation. The BS was developed following a modular and open architecture with the possibility of full customization to operate as stand-alone solution and integration into robotic assistive devices, namely SmartOs system.

User-oriented strategies are implemented to indicate the user when and how the foot-floor contact should be made and, then, how to, autonomously, follow the orthosis trajectory during trajectory tracking control. Also, this dissertation aims the innovative development of therapist-oriented strategies so that the

therapist can participate in the therapy and provide accurate instructions to the patients towards a long-term and efficient gait recovery. The developed BS allows ambulatory use to enable daily practice, and it is based on a user-centered design to maximize the user's acceptability and system's usability.

To reach this main goal, it is necessary to achieve the following step-goals:

- **Goal 1**: Literature review of the most recent developed BSs for post-stroke gait rehabilitation in the presence or absence of robotic assistive devices. This state-of-the-art analysis aims to identify the sensors, stimulators, biofeedback strategy, and the training and retention protocols that have been used. The results from the training and retention experimental tests should be analysed to understand which are the effects, promising features, and improvements that may be reached due to biofeedback therapy. This is addressed in Chapter 2.
- **Goal 2**: To explore and set the instructions and directions which are useful and priority to give to the user (user-oriented strategies) and to the therapist (therapist-oriented strategies) through the biofeedback to enhance the SmartOs rehabilitation achievements. The BS should comprise a user-oriented program to improve, progressively, the human-orthosis interaction with low cognitive effort. This is addressed in Chapter 3.
- **Goal 3**: To design and develop the hardware interfaces for the BS, considering that the system should be modular, robust, easy to use, comfortable, allow ambulatory use, multitasking and to be easily integrated into SmartOs architecture. This is addressed in Chapter 4.
- **Goal 4**: To develop and implement the user-oriented and therapist-oriented strategies (which sensors, which stimulators, how should they be modulated, when should they be enabled) based on a Finite State Machine following the user-oriented recovery program of Chapter 3, and its integration in the SmartOs architecture. The strategies should be easily understandable, intuitive, require little cognitive effort and allow multitasking. This is addressed in Chapter 5 and Chapter 6.
- **Goal 5**: To validate the BS effects on orthotic-based gait rehabilitation involving healthy subjects. The validation protocol should be developed and performed in order to prove the system's effectiveness. Also, the validation should englobe the user's appreciation of the usability of the system through a questionnaire. This is addressed in Chapter 5 and Chapter 6.

1.3 Research Questions

In order to achieve the main goal, the following Research Questions (RQs) were identified and answered:

- **RQ1**: How have the state-of-art BSs been designed and applied to reinforce post-stroke gait rehabilitation? The answer is included in Chapter 2.
- **RQ2**: How can the BSs contribute to gait rehabilitation assisted by active orthoses (AOs) using the trajectory tracking control? The answer is included in Chapter 3.
- **RQ3**: Does the BS improve, efficiently, the human-orthosis interaction? The answer is included in Chapter 5 and 6.

1.4 Contribution to Knowledge

The main contributions of this dissertation to knowledge are:

- A review of the most recent developed BSs applied in balance, non-robotic gait and robotic gait rehabilitation to improve the motor recovery of stroke survivors;
- A novel wearable BS including a user-oriented program to improve, progressively, the human-orthosis interaction involving a low cognitive effort;
- A wearable, stand-alone and modular BS programmed with user-oriented biofeedback strategies to teach the user when and how foot-floor contact should be made, how to achieve a symmetric gait, and how to, autonomously, follow the SmartOs AFO trajectory, improving the human-orthosis interaction;
- A wearable, stand-alone and modular BS programmed with therapist-oriented biofeedback strategies, which follow the user-oriented strategies, so that the therapist can provide effective instructions to the patients, improving the human-orthosis interaction;
- Evidence highlighting the effectiveness of BS to teach the orthosis's users about the direction of movement and the needed muscular strength along with the gait cycle, improving the human-orthosis interaction;
- Evidence highlighting the effectiveness of BS to promote the participation of the therapist during orthotic gait rehabilitation.

The work developed during this dissertation allowed the publication of the following conference papers:

- **C. Pinheiro**, J. M. Lopes, L. Moreira, D. Sanz-Merodio, J. Figueiredo, C. P. Santos, E. Garcia, "Kinematic and kinetic study of sit-to-stand and stand-to-sit movements towards a human-like skeletal model", *IEEE 6th Portuguese Meeting on Bioengineering* (ENBENG), Lisbon, 2019.

- L. Moreira, **C. Pinheiro**, J. M. Lopes, D. Sanz-Merodio, J. Figueiredo, C. P. Santos, E. Garcia, "Study of Gait Cycle Using a Five-Link Inverted Pendulum Model: First Developments", *IEEE 6th Portuguese Meeting on Bioengineering* (ENBENG), Lisbon, 2019.
- J. M. Lopes, L. Moreira, **C. Pinheiro**, D. Sanz-Merodio, J. Figueiredo, C. P. Santos, E. Garcia, "Three-Link Inverted Pendulum for Human Balance Analysis: A Preliminary Study", *IEEE 6th Portuguese Meeting on Bioengineering* (ENBENG), Lisbon, 2019.

Furthermore, this dissertation allowed the submission of the following journal article:

- **C. Pinheiro**, J. Figueiredo, C. P. Santos, "Biofeedback systems for post-stroke motor rehabilitation: A review", *Topics in Stroke Rehabilitation*, 2019 [IF = 1.964; Q1 – Community and Home Care, Q2 – Neurology, Q2 – Rehabilitation]

1.5 Dissertation Outline

This dissertation is organized in 5 chapters, as follows.

Chapter 2 presents the state of the art of the BSs developed for post-stroke balance, gait and orthotic rehabilitation. It is presented and discussed the sensors and the stimulators of each BS, the validation protocol and the related results with post-stroke participants.

Chapter 3 addresses the description of the system, the SmartOs and the developed BS. Relatively to the SmartOs, firstly, it is presented a general overview of the tools and features included and, secondly, it is described, in detail, the SmartOs functioning during trajectory tracking control. Lastly, the strategies and components of the developed BS are introduced.

Chapter 4 presents the hardware included in the developed BS. Each component is technically characterized, and its need is justified, highlighting the features of the resulted system.

Chapter 5 comprises, firstly, the description of each foot-floor contact biofeedback strategy, user and therapist-oriented strategies, explaining and justifying how and when the stimuli are enabled during the therapy. Secondly, it is described the validation protocol executed by healthy participants. Lastly, the results of the experimental procedure are presented and discussed.

Chapter 6 describes the interaction-based biofeedback strategies, the joint motion and user participation strategies, and it englobes the same sections as the chapter 5.

Chapter 7 addresses the conclusions of this dissertation, answering the research questions and appointing future work.

2. REVIEW ON BSS FOR POST-STROKE GAIT REHABILITATION

For future research in BSs for post-stroke gait rehabilitation, it is important to understand the state of development of these systems in order to conclude about which are the achievements and the limitations that must be overcome. Thus, this chapter aims to present and analyse the most recent developed BSs to improve the motor recovery of stroke survivors. This review identifies, following this order, the sensors and stimulators used in the BSs, the biofeedback strategy (that explains how the sensor's information is used to enable the stimulus), the training and retention protocols with post-stroke subjects and the BSs' effects in post-stroke gait recovery. Then, the following questions were investigated and answered: "which are the sensors and stimulators included in the BSs and where are they placed?"; and, "how these systems have been applied to reinforce post-stroke motor rehabilitation?". In the end, the conclusions of this chapter are presented.

2.1 BSs: sensors and stimulators

Table 2.1 shows the elected operation mode of the reviewed BSs (namely, vibrotactile, sonorous, visual and electrotactile), and the included stimulators and sensors. Regarding the stimulators, the device (e.g., eccentric rotating mass (ERM) motor [22], [28], screen [23]–[27], speaker [21], [23] and electrode pads connected to an electrotactile unit [21]), and its location (treadmill [23]–[27] and user's body such as back [21], wrist [28], shank [22] and thigh [21]) were identified. Note that the electrotactile unit consists of a switched-mode DC-DC converter that provides an electric stimulation to the user through the electrodes [21]. The ERM motors, in the study [22], were allocated around the patient's paretic shank with equal distance between motors.

The sensor technology included in the BSs, the respective measure and location were reviewed, as follows. First, force sensitive resistors (FSRs) enable identification of heel-strike (HS) and toe-off (TO) events following two configurations: in the study [21], three at the front towards the toe and three at the back towards the heel on both feet; in the study [22], one on heel, toe, first and fifth metatarsal of both feet. Also, FSR were used to measure medial and lateral plantar forces through the following configuration: one on first and fifth metatarsal heads, respectively, on the paretic foot [28]. Second, two force platforms, embedded on a treadmill, tracked the anterior ground reaction force (AGRF) of each foot [23]. Lastly, the embedded force sensors in the orthoses of the study [23] measured the interaction torque between the orthoses and the user (in hip and knee joints of each leg) [24]–[27]. The interaction torque comprises

Table 2.1 - Systems overview. Each BS is identified by its category: (i) BS applied in non-robotic gait rehabilitation and (ii) BS applied in robotic gait rehabilitation.

BS		Operation mode	Stimulator		Sensor		
Category	Studies		Device	Location	Device	Measure	Location
(i)	[28]	Vibrotactile	1 ERM motor	Paretic wrist	2 FSRs	Medial and lateral plantar forces	Paretic foot
	[23]	Visual and sonorous	Screen and speaker	Treadmill	2 Force platforms	AGRF	Treadmill
	[21]	Sonorous and electrotactile	Speaker and electrotactile unit	Back and non-paretic thigh	6 FSRs	HS and TO events	Feet
	[22]	Vibrotactile	6 ERM motor	Paretic shank	4 FSRs	HS and TO events	Feet
(ii)	[24]–[27]	Visual	Screen	Treadmill	Force sensors embedded in an active orthosis	Interaction torque between orthosis and its user	Orthosis

the moments generated by the user's muscles but, also, the gravitational and inertial components, and moments resulting from viscoelastic effects in the joint surrounding tissue [27].

2.2 Biofeedback strategy

Once the robotic devices are, increasingly, being integrated into everyday clinical practice because they offer an intensive, user-oriented and accurate repetitive training [15], the reviewed studies were organized into two categories according to BS's application goal, as follows: (i) BS applied in non-robotic gait rehabilitation (4 BSs [21]–[23], [28]) and (ii) BS applied in robotic gait rehabilitation (1 BS [24]–[27]).

Non-robotic gait rehabilitation

In the study [28], the ERM motor is activated at 220 Hz when the medial plantar force is less than 50% of the lateral plantar force (Figure 2.1A). In the study [22], the motors were activated at 200 Hz through two different modes: stance phase mode - the motors are activated at heel-strike event and remain during non-paretic limb stance time; swing phase mode - the motors are activated during swing phase according to the symmetry ratio (i.e., if the measured symmetry ratio approaches to the target symmetry ratio, the activation frequency of the BS decreases) and the non-paretic limb swing time (Figure 2.1B).

The BS from [21] (Figure 2.1C) uses a sonorous stimulus at 200 Hz. This stimulus is activated according to the above mentioned stance phase mode [21]. Additionally, if the swing phase time of the paretic leg exceeds the swing phase time of the non-paretic leg, the sonorous and an electrotactile stimulus are activated until the paretic leg's heel-strike detection – swing phase mode [21]. The electrotactile stimulus has 115 mA maximum current, 80-250 μs pulse width and 250 Hz frequency [21]. It was regulated in order to provide only a tingling sensation to the user, without stimulating any muscular activity [21]. The stance and swing times are predefined values, thus, they are not adaptative to the user's gait speed change [21], in opposite to [22].

In the study [23], the paretic leg's AGRF data is visible in real-time on a screen through the distance between a symbol x, which indicates the current AGRF, and bars, which represent the target AGRF range (i.e., is a 6-Newton error-tolerance range centred at the AGRF target) (Figure2.1D). Moreover, when the user achieves the target AGRF range, an audible tone is produced[23]. Five AGRF targets, $target\ AGRF$, were calculated through the AGRF peaks from the paretic, $paretic\ AGRF$, and non-paretic, $nonparetic\ AGRF$, legs acquired during a baseline trial (Equation 2.1). The subjects performed a trial for each AGRF target to select the adequate level of

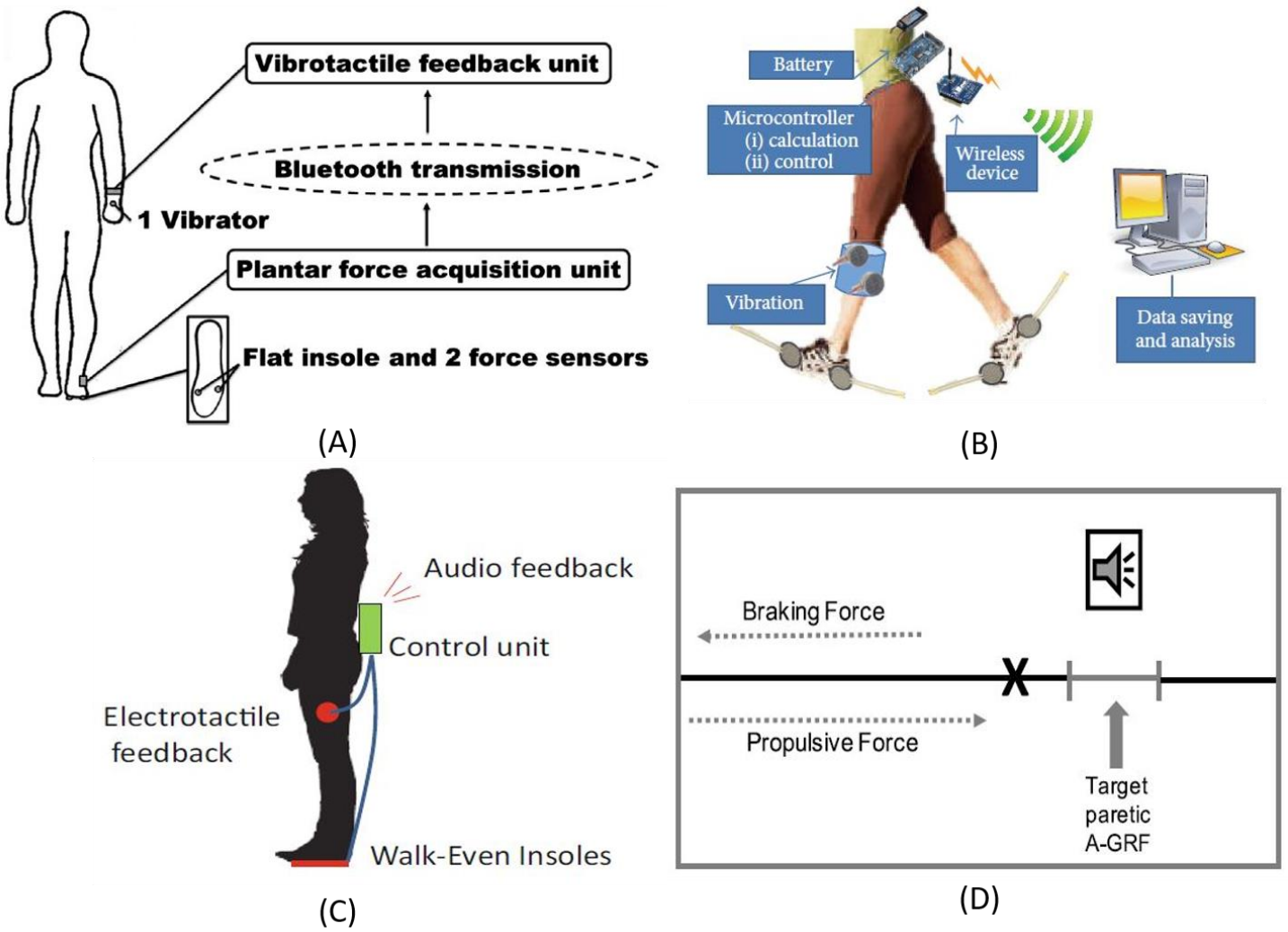


Figure 2.1 – BSs applied in non-robotic gait rehabilitation. (A) Wrist vibrotactile BS from [28]; (B) Shank vibrotactile BS from [22]; (C) Sonorous and electrotactile BS from [21]; (D) Visual and sonorous BS from [23].

challenge, i.e., the trial in which the subject achieved the target range in more than 50% of the performed gait cycles [23].

$$target\ AGRF = paretic\ AGRF + n(nonparetic\ AGRF - paretic\ AGRF); \quad n = 0.2, 0.4, 0.6, 0.8, 1.0 \tag{2.1}$$

Robotic gait rehabilitation

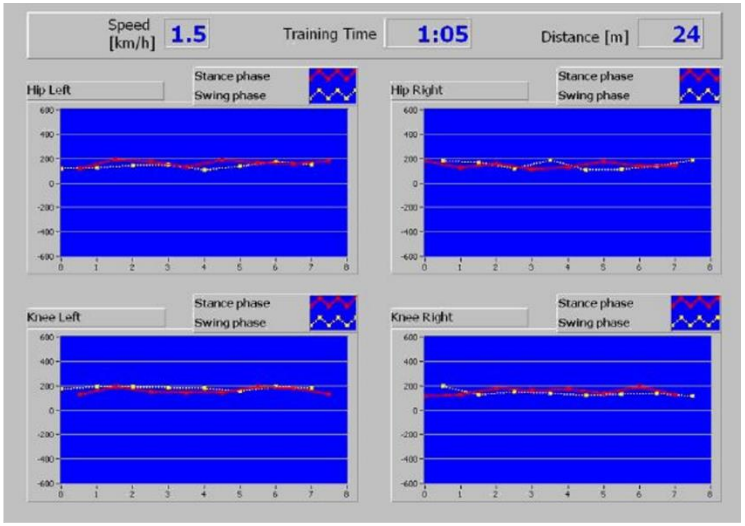
A BS has been applied in robotic gait rehabilitation fostered by active hip and knee orthoses. The orthoses are actuated in the sagittal plane through linear drives and guided the subject with high impedance [24]. The high impedance control strategy permits to detect better changes in the subject behaviour because small deviations lead to large counteracting torque by the robot [26]. In this biofeedback category, two different biofeedback displays were proposed (Figure 2.2A) [24]. The first presents more technical information for the therapists through graphs for each joint, and four biofeedback values are presented per step for swing and stance phases, separately (Figure 2.2B) [24]. The second display provides more intuitive content for the patient, i.e., an updated every step smiley with mouth shape varying according to the average biofeedback values (arc length), threshold (arc pointing downward or upward) and scaling factors set by the therapist (Figure 2.2C) [24].

The biofeedback values, $B_{i,j}$, are weighted averages of the measured interaction torque, F_i, measured by the orthoses' embedded force sensors (Equation 2.2) [24], [26].

$$B_{i,j} = \frac{\sum_k w_{i,j}(t_k) \times F_i(t_k)}{\sum_k w_{i,j}(t_k)} \tag{2.2}$$

Where i is the joint ($i = 0$ for hip and $i = 1$ for knee), j is the gait phase ($j = 0$ for stance phase and $j = 1$ for swing phase) and $w_{i,j}$ are the weight functions at times t_k (1kHz sample frequency). The weight functions are chosen to lead positive biofeedback values when the patient performs the healthy desired movements. For the hip joint, the healthy desired movements are: extension during stance phase, and flexion during swing phase [24]. For the knee joint, the healthy desired movements are: extension during stance phase, and flexion followed by extension during swing phase [24]. In this way, for the hip joint, the weight function was chosen to be proportional to the angular velocity during all gait cycle with a slight modification in swing phase [24], [26]. The slight modification is the multiplication of the angular velocity by a quenching function in order to reduce the effect of the mid-swing forces mainly resulted from passive motion [24], [26]. For the knee joint, the weight function was chosen to be constant during stance

(A)



(B)

(C)

Figure 2.2 - BS applied in robotic gait rehabilitation. (A) System overview; (B) Therapist-oriented visual biofeedback; (C) Patient-oriented visual biofeedback; From [24].

phase (because it takes the requirement of constant weight bearing better into account) and proportional to the angular velocity during swing phase [24], [26].

2.3 BSs: clinical validation

It was extracted the information concerning the training and retention protocols, stroke participants characteristics and the BS's effects collected along with the study, that is organized in the Table 2.2.

2.3.1 Participants

This state of the art includes 83 stroke subjects (40 acute and 43 chronic) between 41-75 years approximately. Table 2.2 shows the number of stroke subjects who participated in the training tests of each BS. The BS applied in robotic gait rehabilitation was trained with the higher number of stroke survivors (56 subjects) in comparison with the other reviewed BS, which involved 4 to 9 participants inclusive. Although the study [25] included acute patients, most of the studies involved participants that have suffered the stroke more than 6 months. Moreover, the most reported inclusion criteria are no cognitive impairment and no orthopaedic or other neurological impairment that would affect gait function.

2.3.2 Training and retention protocols

Table 2.2 shows the duration and frequency of the training sessions and indicates the occurrence or not of the retention tests per BS.

Non-robotic gait rehabilitation

Only 1 training session was performed with the BSs from studies [28], [23] and [22]. In [28], the training session involved the execution of 5 trials of 7 m walking each at a self-selected speed in two conditions: with and without the BS. The sequence of the conditions was randomly assigned to each participant with a 10 min rest between the conditions [28]. In [22], the training session involved the performance of 6 trials of 6 m walking each at a self-selected speed without the BS (2 trials) and, then, with the BS in stance phase (2 trials) and swing phase modes (2 trials). If needed by the participants, it was allowed the use of their walking aid cane [22]. In [23], the training session involved the performance of 1 trial and 5 trials of 6 min walking each on the treadmill at a self-selected speed without and, then, with the BS, respectively. The biofeedback was provided with an alternating 1 min on and 1 min off protocol (i.e. the activation period of the BS was 1 minute) [23]. After 2 min seated break, the retention tests were performed to evaluate the short-term recall of the trained gait pattern [23]. The subjects were instructed to perform a 30 s walking trial on the treadmill at a self-selected speed without the BS,

maintaining the gait that they used during the training [23]. More two retention trials were performed at 15- and 30-min post-training with seated breaks between them [23].

The participants of the study [21] performed a total of 16 training sessions with the BS: twice sessions a week during 8 weeks. Two participants were randomly chosen to the control group and the remaining belong to the experimental group [21]. The control group received conventional gait training without the BS while the experimental group received gait training with the BS during 20 min per session [21]. Two subjects of the experimental group received biofeedback during stance phase and the remained subjects of the same group received biofeedback during swing phase [21]. Before each training session, all the subjects received 20 min of strength training [21].

Robotic gait rehabilitation

Relatively to the BS applied in robotic gait rehabilitation, before the training, it was given time to each subject to familiarize with the orthotic system [25]. Then, the subjects were instructed to follow the orthosis with the BS cues. The orthosis assisted according to the subject-specific pattern, with body weight support, during 30 min [25]. A total of 8 training sessions were performed and at least 3 sessions were performed over a time period of 14 days [25]. The level of challenge increased between sessions: the walking velocity increased (Session 1: 1.8 ± 0.3 km/h; Session 8: 2.4 ± 0.4 km/h) and the guidance force (supporting force of the robot) decreased (Session 1: 100 ± 0.0 %; Session 8: 92.3 ± 11.3 %) [25]. Additionally, all the subjects received 3-4 h per week of conventional physiotherapy and occupational therapy [25].

2.4 BSs: effects in post-stroke gait recovery

Different outcomes, as listed in Table 2.2, were measured to investigate the evidence of BS's into post-stroke gait recovery.

Non-robotic gait rehabilitation

Study [28] reported that the use of the biofeedback in gait training significantly decreased the paretic foot inversion peak (p-value = 0.012), the non-paretic knee flexion peak during swing-phase (p-value = 0.009) and the non-paretic hip abduction peak during stance phase (p-value = 0.017), and significantly increased the paretic total foot-floor contact area (p-value = 0.001) and paretic plantar pressure peak at medial midfoot (p-value = 0.001). The walking speed did not significantly change (p-value > 0.05) [28]. These data were acquired through an eight-camera three-dimensional motion capture system (Vicon Nexus 1.8.1., Vicon Nexus™, Vicon Motion Systems Ltd., UK) and a pedar-x system (Pedar™, novel GmbH, Munich, DE) [28].

Table 2.2 – Overview of the experimental results. Each BS is identified by its category: (i) BS applied in non-robotic gait rehabilitation and (ii) BS applied in robotic gait rehabilitation.

BS		Stroke participants	Biofeedback training		Retention	Biofeedback effects
Category	Studies		Duration	Frequency		
(i)	[28]	8 (7.5 years)	7 m	5 trials	No	• Significantly decreased: ○ Paretic foot inversion peak during swing phase: 0.012 p-value ○ Non-paretic knee flexion peak during swing phase: 0.009 p-value ○ Non-paretic hip abduction peak during stance phase: 0.017 p-value • Significantly increased: ○ Paretic total foot-floor contact area: 0.001 p-value ○ Paretic plantar pressure peak at medial midfoot: 0.001 p-value
	[23]	9 (54±12.4 years)	6 min	3 trials	Yes	• Significantly increased: ○ Paretic AGRF peak: < 0.001 p-value ○ Paretic trailing limb angle: 0.021 p-value ○ Paretic ankle plantarflexor moment: < 0.044 p-value ○ Non-paretic step length: 0.03 p-value
	[21]	6 (51-66 years)	20 min	Twice a week for 8 weeks	No	• Significantly decreased asymmetry ratio: 0.016 p-value • Higher increase in the experimental group: ○ Paretic foot pressure: 51% experimental group and 26% control group ○ Heel to forefoot transfer point: 17% experimental group and 6% control group
	[22]	4 (52-75 years)	6 m	2 trials per mode	No	• Significantly increased symmetry ratio through stance mode BS: 0.0493 p-value • Significantly increased symmetry ratio through swing mode BS: 0.0427 p-value
(ii)	[24]–[27]	56 (40 acute 16 chronic) (61.34±11.52 years)	30 min	8 sessions	No	• Negative average biofeedback values: range between -200 and 0

The results from study [23] revealed that the biofeedback significantly increased the paretic AGRF peak (p-value < 0.001), the paretic trailing limb angle (angle between the laboratory vertical axis and vector joining the fifth metatarsal and greater trochanter markers) (p-value = 0.021), the paretic ankle plantarflexor moment (p-value < 0.044) and the non-paretic step length (p-value = 0.03), and no significant changes were reported in the other leg [23]. Additionally, there was a significant paretic AGRF peak increase in the second and third retention tests comparing to pre-training (p-values < 0.001). The AGRF peak inter-individual variability was considerable [23].

The study [21] demonstrated that the asymmetry ratio (1-paretic stance time/non-paretic stance time) improved significantly between pre- and post-training with the BS (p-value = 0.016). Also, the authors reported that the average paretic foot pressure and the heel to forefoot transfer point (measured by the TekScan insole system) increased and decreased, respectively, more in the experimental group than in the control group. Between pre- and mid-training, it was not observed significant improvements of the asymmetry ratio (p-value > 0.05) [21].

In [22], better effects were achieved with biofeedback in comparison with no biofeedback because it was reported a significant increase of the symmetry ratio (stance time division between non-paretic and paretic limb) between the no biofeedback training and the biofeedback training in stance phase mode (p-value = 0.0493) and swing phase mode (p-value = 0.0427), respectively. Pearson correlation coefficients were found to be linear for the mediolateral tilt and acceleration (measured through a smartphone attached on waist) [22]. However, the symmetry ratio equal to 1 was not achieved and large deviations occurred [22].

Robotic gait rehabilitation

The results from [25] are one average biofeedback value for each training session, where the biofeedback values are weighted averages of the measured interaction torque [24], [26]. It was noticed that only negative average biofeedback values were obtained, indicating that the subjects were more inactive than active possibly due to their affected leg [25]. Through comparison of these values between training sessions, it was noticed a decrease after the first session, possibly due to the walking speed's increase and guidance force's decrease between sessions, and a slow increase from third to fifth sessions, indicating progress [25]. The Table 2 shows the range in which the obtained biofeedback values are included.

2.5 Discussion

With this literature analysis, the following questions were investigated and answered: “which are the sensors and stimulators included in the BSs and where are they placed?”; and, “how these systems have been applied to reinforce post-stroke motor rehabilitation?”.

2.5.1 Which are the sensors and stimulators included in the BSs and where are they placed?

The literature review identified that, in the non-robotic gait rehabilitation category, the vibrotactile and sonorous biofeedback are the most applied biofeedback modes for post-stroke motor recovery regarding the observed biofeedback modes (vibrotactile, sonorous, visual and electrotactile). The vibrotactile and sonorous modes allow to a wearable and low-cost BS [22], [28]. Also, they are fast perceived and allow multitasking [29]. Moreover, it can be interesting to use two modes in the same BS, as proposed in [23], since it results on a reduced cognitive load for the user when compared to the use of only one mode, as discussed in [18]. The combination of the sonorous and vibrotactile stimuli seems promising, since the visual and vibrotactile stimuli have, respectively, a higher and a lower reaction time than the sonorous stimulus [29]. Although, all the reviewed biofeedback modes (vibrotactile, sonorous, visual and electrotactile), in the non-robotic gait rehabilitation category, showed to be useful to improve post-stroke gait pattern [21]–[23], [28]. In the robotic gait rehabilitation category, only the visual mode was implemented and showed to be a powerful mode to present complete technical information [25].

Table 2.1, it can be concluded that each mode has a specific device to provide the stimulus. Vibrotactile systems endow ERM motors activated around 200 Hz in [22], [28]; the sonorous systems include speakers, where the sonorous stimuli are tones (200 Hz in [21]); the visual systems use screens to provide graphs [23], [24] or a smiley representation as visual stimuli [24]; and the electrotactile systems comprise electrodes and boost convert circuits to foster stimulus modulated according to 115 mA maximum current and 250 Hz pulse frequency [21]. Moreover, most of the BSs use wearable actuators on the upper limbs (back [21] or wrist [28]) or on the lower limbs (shank [22], thigh [21]), contributing to ambulatory application of the BSs. Only the BSs that included visual stimulus are non-wearable, limiting the rehabilitation to indoor conditions and compromising daily assistance [24].

Regarding the sensor technology, in the non-robotic gait rehabilitation category, the FSRs and force platforms are used [21]–[23], [28]. Although both sensors have the capability of analyse gait events and plantar forces, the FSRs were most applied than force platforms since the latter is a non-wearable sensor technology [30]. The FSRs are placed on the user’s feet according to a specific configuration which depends its application: the most used application is to detect the HS and TO events (three at the front

towards the toe and three at the back towards the heel [21] or one on heel, toe, first and fifth metatarsal [22]) but they are also used to measure the medial and lateral plantar forces (one on first and fifth metatarsal heads, respectively [28]). In the robotic gait rehabilitation category, the force sensors embedded in the orthoses are the ones used to measure the user-orthosis interaction torque [24]–[27].

2.5.2 How the BSs have been applied to reinforce post-stroke motor rehabilitation?

The reviewed BSs were activated when a predefined condition happened. This condition can be periodic (e. g., occurrence of HS or TO events [21], [22], paretic leg AGRF [23] and biofeedback values based on interaction torque data [24]–[27]) or not (e. g., medial plantar force is less than 50% of the lateral plantar force [28], if the swing phase time of the paretic leg exceeds the swing phase time of the non-paretic leg [21] and when the user achieves the target AGRF range [23]). The latter BSs aim to teach the users according to their performance in opposite to BSs based on periodic conditions. Moreover, the periodic stimulus activation of the BS can decrease according to the increase of the user learning, as reported in [22], which helps the progress of the user's motor function recovery, as discussed in [18], because avoid user dependency on the system.

In most studies, the stimuli remain until the condition is not verified (until the medial plantar force equals the lateral plantar force [28], until the paretic leg swing phase time equals the non-paretic leg [21] and until the user loses the target AGRF range [23]). However, in [21] and [22], the stimulus duration is a predefined value (non-paretic stance time), which can be updated along the gait (if the non-paretic stance time changes during the training, the stimulus duration is updated in the next stride [21]) or not, as in [22], leading to overestimation or underestimation (i.e., the paretic leg's biofeedback is not in accordance with the non-paretic leg behaviour).

Relatively to the training protocols, most of the studies asked the participants to perform gait training in the presence and absence of biofeedback. Only the study [21] created a control group. The number of training sessions varied from 1 [22], [23], [28] to 16 (twice sessions a week for 8 weeks [21]), indicating that long-term evaluations are needed. The maximum total training time with the BS was 320 minutes in the study [21]. The retention tests were only performed by the study [23], indicating that the motor relearning study with the remain BSs is missing. Moreover, the study [23] promoted the motor relearning through the implementation of the time on and time off training protocol.

From the reported biofeedback effects in post-stroke non-robotic gait rehabilitation, an increased gait symmetry was reported in [28], [23], [21] and [22]. Besides that, as the authors say, the non-significant change in the walking speed in [28] proved the intuitive feature of the BS because the subjects

did not need to walk more slowly when paying attention to the vibrotactile cues on the wrist. Moreover, the founded linear Pearson correlation coefficients in [22] shows that the balance of the body is not disturbed regardless of the shank vibrations. Furthermore, the results from the retention test in [23] indicate that healthy gait patterns (AGRF target range achievement) were learned during the training. Therefore, the BSs reveal to be a promising tool to improve the gait pattern of post-stroke patients, enhancing the motor learning.

Despite the successful effects in gait recovery, it is important to notice that, in [21], no significant improvement were found between pre- and mid-training which indicates that 4 weeks of training is not enough to improve the gait symmetry. Similarly, the study [22] reported that the expected symmetry ratio equal to 1 was not achieved after one training session. According to these findings, it can be concluded that the training period is a determining factor to the success of the BS and long-term training periods should be performed, as conclude in [18]. On the other hand, the considerable inter-individual variability, in [23] and [22], highlights the need to adjust and tailor the biofeedback (AGRF target range [23] and symmetry ratio target [22]) to the current patient needs, improving the target, gradually, along the recovery.

In the robotic gait rehabilitation category, the BSs seem to have potential to accelerate the motor recovery once they, effectively, motivate the patients to actively move according to the healthy gait pattern imposed by the robotic devices [25]. However, the reviewed BS did not achieve significant improvements possibly due to the lack of training [25]. This result and the lack of BSs in this category indicate that there is a need to focus on the development of these type of systems.

Some of the reported limitations are the lack of a control group [23], the small number of participants [21]–[23], [28], and no study of the long-term effects of the BS [22], [23], [25], [28], as concluded in [18]. Also, it was reported the need to define user-specific targets that are updated according to the imminent user gait performance [23], [28] and the need to study the immediate effects of biofeedback within-session time course [23].

2.6 Conclusions

In the non-robotic gait rehabilitation field, there is a prevalence to apply wearable and economic vibrotactile and sonorous BSs. The vibrotactile ones are constituted by ERM motors attached to the user's wrist or shank. The sonorous BSs include speakers attached to the treadmill or user's back. However, visual and electrotactile biofeedback modes showed, also, positive effects in patient's motor recovery. In

robotic gait rehabilitation, screens attached on the treadmill are used. Since all the visual BSs are non-wearable, a wearable visual BS is needed.

Under more than one biofeedback goal, there is evidence to prefer the combination of different biofeedback modes to reduce the user's cognitive load. As future direction, the combination of vibrotactile and sonorous stimuli seem to have potential due to its reduced reaction time comparing to the visual stimulus. Due to this and because there is a lack of BS to be applied in robotic gait rehabilitation, the design of a vibrotactile or/and a sonorous BS for this field seems promising.

The wearable FSR sensor is the most used sensor in BS's application for post-stroke non-robotic gait rehabilitation. Attached on the patient's feet, this sensor provides foot-floor contact information. In robotic gait rehabilitation, the force sensors embedded in the orthoses are the used sensors to measure the user-orthosis interaction torque.

Additionally, this literature analysis highlights the relevance of long-term retention tests to evaluate the motor learning after an extensive training period with many stroke survivors.

Through the reported effects of the BSs, it can be concluded that they are a promising tool to increase gait symmetry and weight bearing during non-robotic gait rehabilitation, and to enhance the user active participation during robotic gait rehabilitation.

3. SYSTEM DESCRIPTION: SMARTOS AND BIOFEEDBACK SYSTEM

The main outcome of this dissertation is a biofeedback system designed to be used with the ankle orthosis of SmartOs system during the gait rehabilitation of stroke survivors. In this manner, this chapter presents the already developed SmartOs system and details the trajectory tracking control that is used to validate the presented BS. The chapter ends with a general overview of the developed biofeedback system.

3.1 SmartOs: Smart Control of a Stand-Alone Active Orthotic System

3.1.1 System's overview

The SmartOs is a modular, wearable and innovative assist-as-need active orthotic system for robotic-based gait training of pathological users. This technological device allows repetitive gait training according to the user's needs and abnormal gait pattern correction. Also, it provides objective gait analysis of the user's motor ability. According to this, the SmartOs is a powerful tool for pathological users fast achieve functional motor recovery.

The SmartOs is composed by a wearable motion lab, ankle-foot and knee active orthoses, gait analysis tools, mobile and desktop graphical applications, and power supply system.

The **wearable motion lab** monitors in real-time the patient's motor ability. It includes ergonomic, stand-alone and wearable sensory systems, such as: (i) GaitShoe to measure foot-ground contact through FSRs placed on heel and toe; (ii) InertialLAB to monitor the biomechanical motion of limbs; (iii) MuscLAB to, fast and easily, monitor the muscle activation; (iv) Electromyographic system to, rigorously, monitor muscle activation.

The **ankle-foot orthosis** is a right-side module of the lower-limb H2-exoskeleton (Technaid S.L., Spain) and aid the gait task in the sagittal plane for gait speeds between 0.5 and 1.6 km/h.

The orthosis is composed by an electrical actuator (flat brushless DC motor EC60-100W, Maxon) coupled to a gearbox (CSD20-160-2A strain wave gear, Harmonic Drive), capable of providing an average torque of 35 Nm and peak torque of 180 Nm, and embedded sensors. The embedded sensors are: (i) potentiometer to measure the joint angle (resolution of 0.5°); (ii) four strain gauges connected in a full Wheatstone bridge to measure the user-orthosis interaction torque (resolution of 1 Nm); (iii) hall effect sensor to track the motor's angular speed, current and torque; (iv) two FSRs, placed at heel and toe, to measure the ground reaction force.

The **gait analysis tools**, automatically and time-effectively, detect gait events, and recognize the user's motion intention and disability level, using the information from the wearable motion lab and/or orthosis's embedded sensors.

The **mobile and desktop graphical applications** provide intuitive use and full abstraction from the technical aspects of the SmartOs modules. The first allows the system configuration to different therapies and the second allows real-time monitoring of all data generated along with the therapy.

The **power supply system** allows the stand-alone and wearable features of the SmartOs. It includes a lithium iron phosphate battery with 8 h of autonomy and a hardware interface to power up all the SmartOs modules.

The SmartOs **framework** follows a non-centralized architecture, including three different development boards to control the modules:

- Central Controller Unit (CCU) to run gait analysis tools, high-level controllers and to communicate with external graphical applications, on a Raspberry Pi 3 board (Raspberry Pi Foundation, UK);
- Low-level Orthotic System (LLOS) that closely work with the active orthoses and run the low-level and mid-level controllers, on a STM32F4-Discovery board (STMicroelectronics, Switzerland);
- Wearable Motion LAB (WML) that manages the InertialLAB, GaitShoe, MuscLAB and electromyographic system, on a STM32F4-Discovery board (STMicroelectronics, Switzerland).

The Figure 3.1 shows the SmartOs hardware needed for using the BS, namely: the AFO with its embedded strain gauges, the framework composed by the CCU and LLOS to run the trajectory tracking control therapy and the power supply.

In overall, SmartOs works as follows. Through Bluetooth, the therapy's configuration is transferred from the mobile graphical application to the CCU. The CCU, in its turn, sends a command, through UART, to the LLOS, which runs the low-level PID controller. The LLOS is connected to the AFO and its embedded strain gauges through CAN interface. The data from the embedded sensor is transferred from the LLOS to the CCU to be analysed in the end of the therapy.

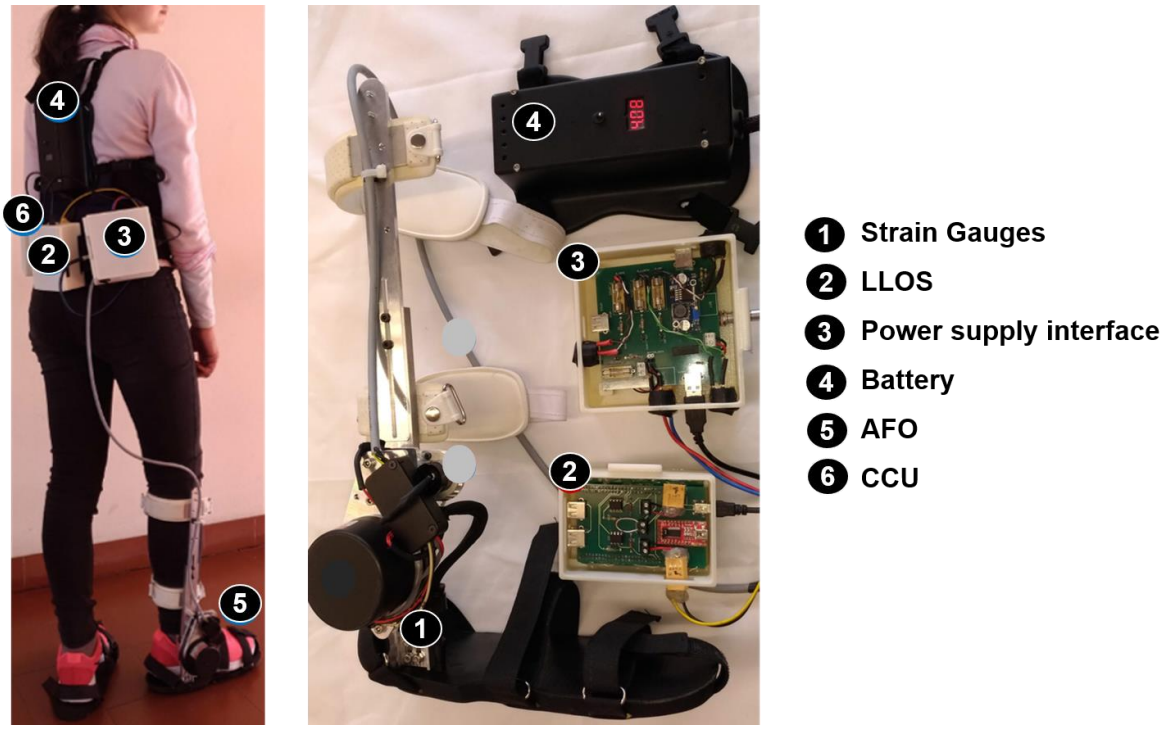


Figure 3.1 - SmartOs AFO with the embedded strain gauges, framework (LLOS and CCU) and power supply.

3.1.2 Trajectory tracking control

The SmartOs follows a bioinspired hierarchical control architecture with three levels (low-level, mid-level and high-level) to generate user-oriented assistive commands set by assistive control strategies.

In the scope of this dissertation, the BS will be applied when the SmartOs assistance follows trajectory tracking control (one of the available assistive control strategies of the SmartOs). The high-level includes a trajectory generator that adjusts the joint sagittal plane gait trajectory according to the user's height and speed, outputting the user-oriented position trajectory, θ_{user}. The mid-level controller sets the AO's reference position trajectory, θ_{ref}, as the user-oriented position trajectory parameterized according to the gait speed. This modulation follows Equation 3.1, where s is the gait speed from 0.5 to 1.6 km/h and t is the time in ms between each point of the reference trajectory. Figure 3.2 shows the reference trajectory of the SmartOs-ankle orthosis composed by 48 samples. The ankle angle is zero when the foot is parallel to the ground. The ankle angle increases and decreases when the foot rotates against and according its weight, respectively.

$$t = -34.62 \times s + 107.31 \tag{3.1}$$

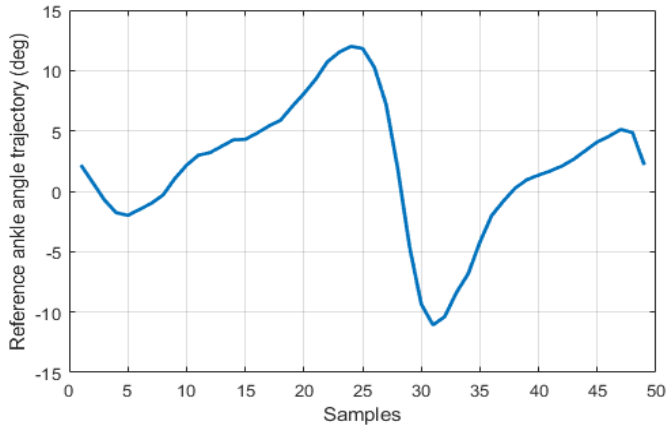


Figure 3.2 - Reference trajectory of the SmartOs-ankle orthosis (deg).

The low-level control is based on a close-loop proportional–integral–derivative (PID) controller. The tuning results from Ziegler-Nichols method for the SmartOs AFO are 90, 1.5 and 1.5 for the proportional, integral and derivative gains, respectively.

As can be seen in Figure 3.3, the output of the PID acts on the orthosis's motor, generating the motor's torque, which in turn, acts on the user's joint to follow a reference trajectory. If the measured joint angle is not equal to the reference joint angle, caused by user-independent motion or reference trajectory variation, the controller corrects this angle trying to impose a healthy gait pattern to the user. Every time that the user does not move according to the reference trajectory, an interaction torque between the user and orthosis results.

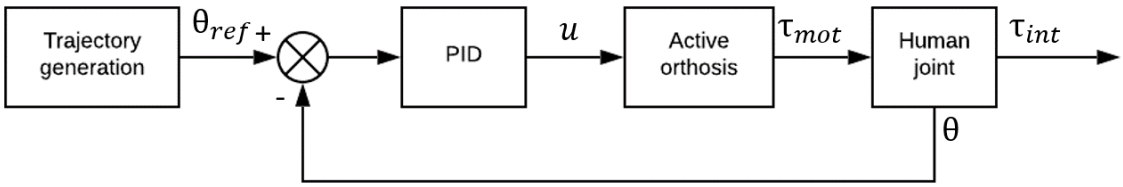


Figure 3.3 - Trajectory tracking control. Θ_{ref} is the reference trajectory, u is the output of the PID controller, τ_{mot} is the torque of the orthosis's motor, τ_{int} is the user-orthosis interaction torque and θ is the measured joint angle.

Relatively to the interaction torque, the more synchronized the user and the orthosis are during walking, the closer to zero is the interaction torque. According to this, the interaction torque increases as the force applied by the user in the orthosis increases during the therapy (Appendix I). This force can come from muscular strength, weight, inertia, and viscoelasticity as described in [27]. The positive and

negative values indicate that the user is applying a force towards the decrease and increase of the reference trajectory, respectively (Appendix I).

3.2 Biofeedback System: General Description

The presented BS was developed to be applied during the ankle orthosis-based gait rehabilitation of post-stroke patients and aims the acceleration of the patient's gait recovery through the improvement of the human-orthosis interaction. With the trajectory tracking control, the patient's ankle-foot complex is manipulated in the sagittal plane, following a predefined healthy reference trajectory. However, the goal of the rehabilitation is not to turn the patient dependent on the orthosis. The goal is to teach the user how to perform a healthy gait pattern. Without effective biofeedback, it is difficult for the users to effectively follow the orthosis's movement, resulting in a high interaction torque between the human and the orthosis (Appendix II).

To ensure that the users actively follow the SmartOs movement, firstly, it is necessary to teach them about when and how should be made the paretic foot-floor contact. Without the BS, this is normally done without great rigor through visual inspection of the orthosis's movement by a therapist, who is familiarized with the orthosis's reference trajectory, and gives instructions to the users. Moreover, since the non-paretic leg is not guided by the orthosis, the BS can teach the users when they should make the non-paretic foot-floor contact to ensure a symmetric gait. After this motor relearning, the user is physically apt to learn how to actively follow the orthosis's healthy pattern, i. e., the direction of movement and the necessary muscular strength to apply along with the gait cycle.

According to these conditions, the BS was designed to include four **user-oriented biofeedback strategies** (Figure 3.4) that should be used in the following order:

1. **Paretic foot-floor contact** biofeedback to repetitively teach the user when and how he/she should perform the paretic foot-floor contact along the gait cycle;
2. **Non-paretic foot-floor contact** biofeedback to repetitively teach the user when he/she should perform the non-paretic foot-floor contact along the gait cycle, aiming a symmetric gait;
3. **Joint motion** biofeedback to teach the user the ankle joint direction of movement along the gait cycle;
4. **User participation** biofeedback to teach the user to exert the needed muscular strength along the gait cycle through contraction of the agonist muscles (gastrocnemius, soleus or tibialis anterior).

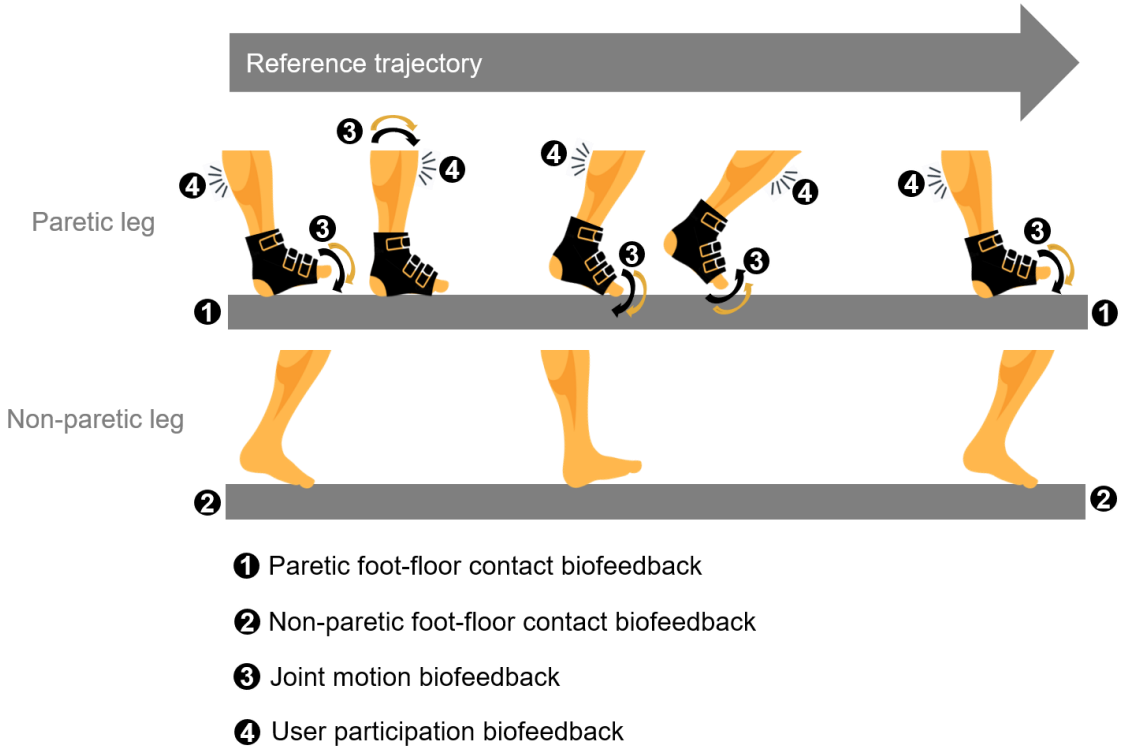


Figure 3.4 – Schematic of all the biofeedback strategies: paretic and non-paretic foot-floor contact, joint motion and user participation. The yellow and black arrows illustrate the direction of movement of the user and orthosis, respectively.

Moreover, **therapist-oriented biofeedback strategies** were developed such that the therapists can, easily and accurately, follow the performance of the users during the use of the biofeedback. The therapists' contribution may help the patients in a complementary way, thus further motivating them, and making them feel safe. In this manner, there is a therapist-oriented biofeedback strategy for each user-oriented biofeedback strategy.

The four biofeedback strategies have been developed aiming the gradual improvement of the human-orthosis interaction, thus decreasing the cognitive effort of the BS. The BS was designed to be comfortable, easy to use, easily understandable, intuitive, to require little cognitive effort and allow multitasking, following a user-centered design.

Figure 3.5 shows an overview of the BS. The system's power supply is a battery coupled to a step-up, allowing stand-alone and compact features of the BS. The microcontroller manages the data from the LLOS and runs the chosen biofeedback strategy, enabling the stimuli as needed. For the user-oriented strategies, the stimulators are ERM motors, driven through specific drives, or headphones, which play a tone saved in the microcontroller memory. For the therapist-oriented strategies, the stimulator is a Red-Green-Blue Light-Emitting Diode (RGB LED). The system is prepared to be integrated into the SmartOs, using the LLOS as the microcontroller, or to be a module, communicating with the CCU through the

FT232R converter. All the components were chosen to allow the wearable, compact, easy to use and comfortable features of the system.

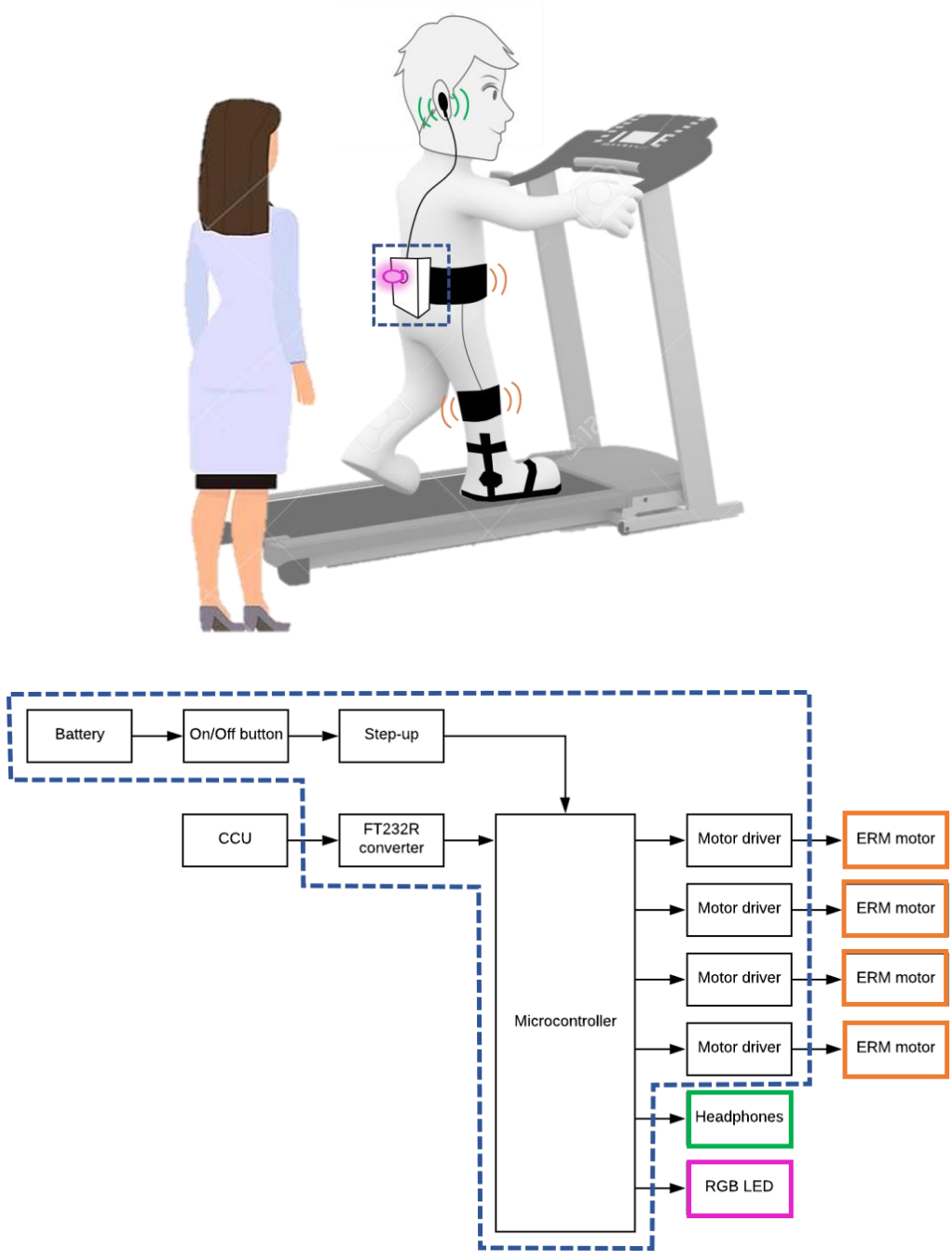


Figure 3.5 – Overview of the biofeedback system.

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4. BIOFEEDBACK SYSTEM'S HARDWARE INTERFACE

This chapter presents the hardware included in the developed BS. Each BS's component is identified, its function is described, and its choice is justified.

The developed BS has three biofeedback's modes: vibrotactile, sonorous and visual. These modes are provided through three stimulators: ERM motors, headphones and RGB LED, respectively. The vibrotactile and sonorous stimuli are more rapidly detected by the human in comparison to the visual one, demanding less cognitive effort. [29]. According to this, the vibrotactile and sonorous stimuli were chosen for the user-oriented biofeedback strategies. On the other hand, the therapist-oriented biofeedback strategies are provided by means of visual stimulus. For this purpose, a RGB LED was used since it is a wearable, easy understandable and accurate solution to help the therapist to follow the performance of the patients so that the therapist can, effectively, participate in the therapy during the use of the BS.

Figure 4.1 presents an overview of the designed and developed hardware interfaces for BS. The BS can be integrated into the SmartOs (Figure 4.1A) or it can function as a SmartOs module (Figure 4.1B), involving different hardware interfaces. In the first case, the BS involves the LLOS as the development board, the associated electronics (LLOS PCB) and it is powered by the SmartOs' power supply system. In the second case, the BS functions as a stand-alone, entailing its own power supply and development board and it has a USB as serial UART interface to communicate with the SmartOs. As it can be visualized, the electronics is centralized in a robust and ergonomic PCB and it is protected by a solid and light 3D printing case to improve its ergonomics and usability. The total weight of the BS is 387 g and 397 g in the first and second case, respectively. During the use of the BS, the electronics is allocated on the user's back through a waist band such that the system does not disturb the user's movements. Each involved component is described below.

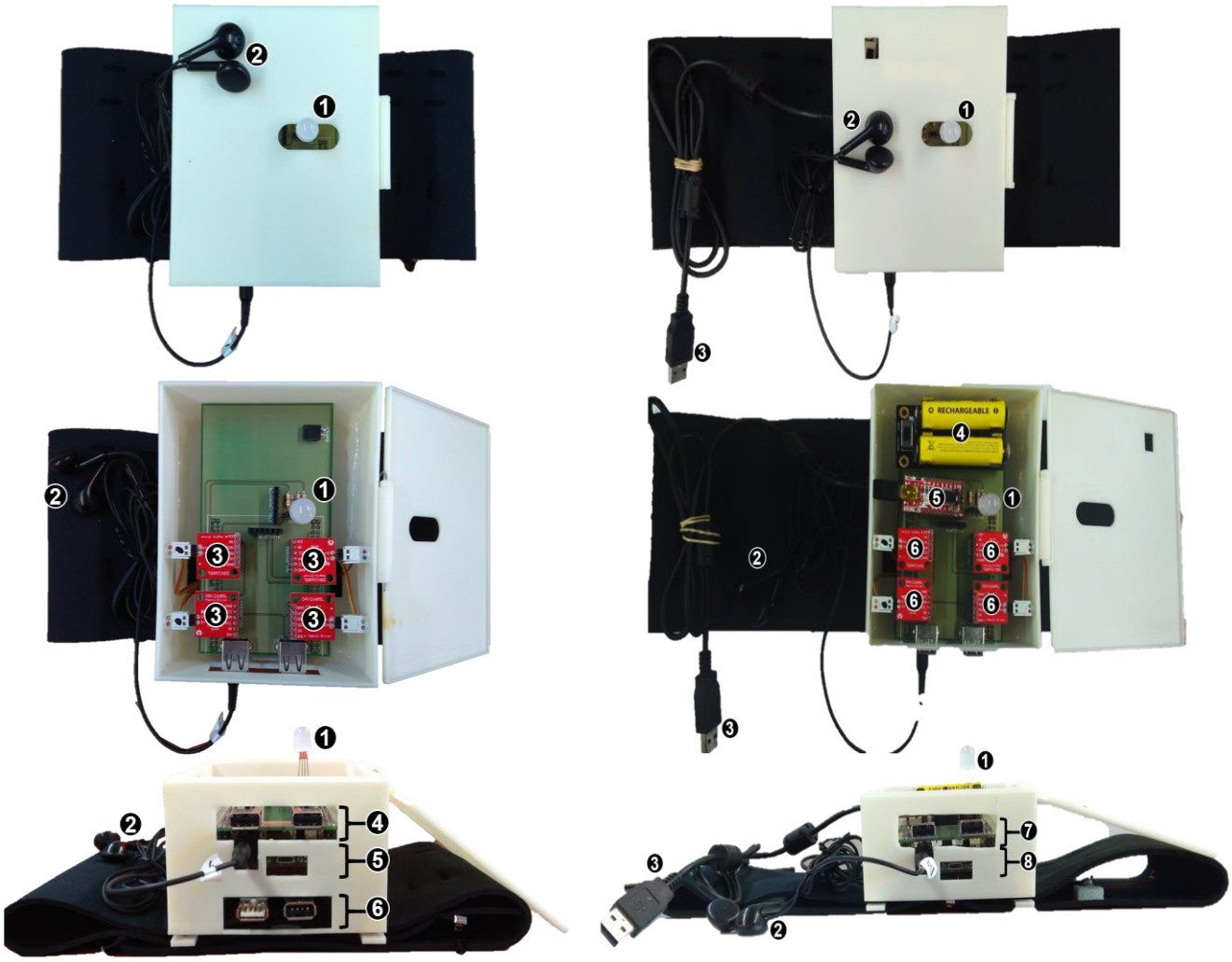


Figure 4.1 - Biofeedback system's hardware interface. (A) The BS when integrated into the SmartOs; (B) The BS functions as a module of the SmartOs.

4.1 Development board

The **STM32F4-Discovery board** (STMicroelectronics, Switzerland) was chosen to be the development board of the BS and it enables the stimuli according to the selected biofeedback strategy. This board handles a STM32F407VGT6 microcontroller (32-bit ARM Cortex® -M4 core) which can run at 168 MHz, has 1-Mbyte flash memory and 192-Kbyte RAM [31]. This board has embedded CS43L22 audio DAC with class D speaker driver integrated and it has I^2C and UART communication interfaces, and an adequate number of timers and I/O pins [31]. Therefore, this board is prepared to produce a sound that can be listened through headphones. The functioning of the motor drivers and the CS43L22 audio codec are controlled through I^2C. Communication with the SmartOs when the BS is used as a module is achieved through UART. When the BS is integrated into the SmartOs, the development board is the LLOS that is, also, a STM32F4-Discovery board. All these features make the STM32F4-Discovery board a low-cost effective solution for this project.

4.2 Power Supply

When used as a stand-alone, the BS is supplied by two rechargeable AA Ni-MH batteries of 1.2 V and 2000 mAh coupled to a 5 V step-up voltage of 1 A maximum output current. This step-up has coupled a support for the batteries, a LED to indicate the low battery state, an ON/OFF button and a LED to indicate the ON state. When the button is turned ON, the STM32F4-Discovery board is supplied and, in its turn, supplies the remaining electronics. This solution is compact and light contributing to the wearable feature of the BS. When the system is integrated in the SmartOs, it is supplied by the wearable SmartOs' power supply interface. Therefore, the BS allows ambulatory use enabling daily practice.

4.3 Communication with SmartOs

The BS is prepared to be integrated into the SmartOs, using the LLOS as the development board, and it is prepared to be used as a module of the SmartOs. The first option makes the SmartOs more compact and, consequently, makes the system easy to use and comfortable. On the other hand, the second option allows the use of the system with other robotic devices. The versatility of the BS allows to expand its use in other applications and markets. The **FT232R** (FTDI, United Kingdom) is a USB to serial UART interface which allows the communication between the LLOS and the STM32F4-Discovery board, when the BS is used as a module.

4.4 Vibrotactile stimulus's hardware interface

The coin shape **ERM motors** (Figure 4.2) (Model 310-122, Precision Microdrives, United Kingdom) were chosen as vibrotactile stimulators because they allow the modulation of the vibrotactile stimulus through the applied voltage [32]. Additionally, the coin shape is comfortable for on body use. Since it is not possible to drive the ERM motors directly from the microcontroller due to the high current draw of the motors, each ERM motor is regulated through a **DRV2605L haptic driver** (Texas Instruments, United States of America) [33]. This driver accepts Pulse Width Modulation (PWM) signals as a control, allows output voltage regulation and advanced driving techniques [33].

The vibrotactile motors are placed on the user's body through waist and shank bands. The vibrotactile bands are, fundamentally, constituted by neoprene, which gives elasticity to the band. This elasticity allows the user's comfort and, also, that the vibrotactile motors stay very close to the skin, facilitating the perception of the vibrotactile stimulus by the user. Also, this elasticity allows the band to fit in different bodies. Therefore, to enable the use of the system for most people, a small and large sizes were design for each band.

The vibrotactile motors are connected to the DRV2605L haptic motor drivers by wires, and the motors and the wires are fixed on the elastic bands through an elastic polyester. As illustrated in Figure 4.2, the wire follows a zig-zag configuration not to limit the elasticity of the band. Moreover, the foam between the vibrotactile motors and the neoprene prevents the propagation of the vibrotactile stimulus through the band, facilitating its spatial perception.

In both waist and shank bands, the motors are equally spaced in accordance with the reviewed spatial resolution of the waist [34] and shank [35], [36], to facilitate its spatial discrimination and perception. Moreover, it is important to notice that the motors' location remains the same between users since the band was designed to expand equally in different directions and it closes through a zipper.

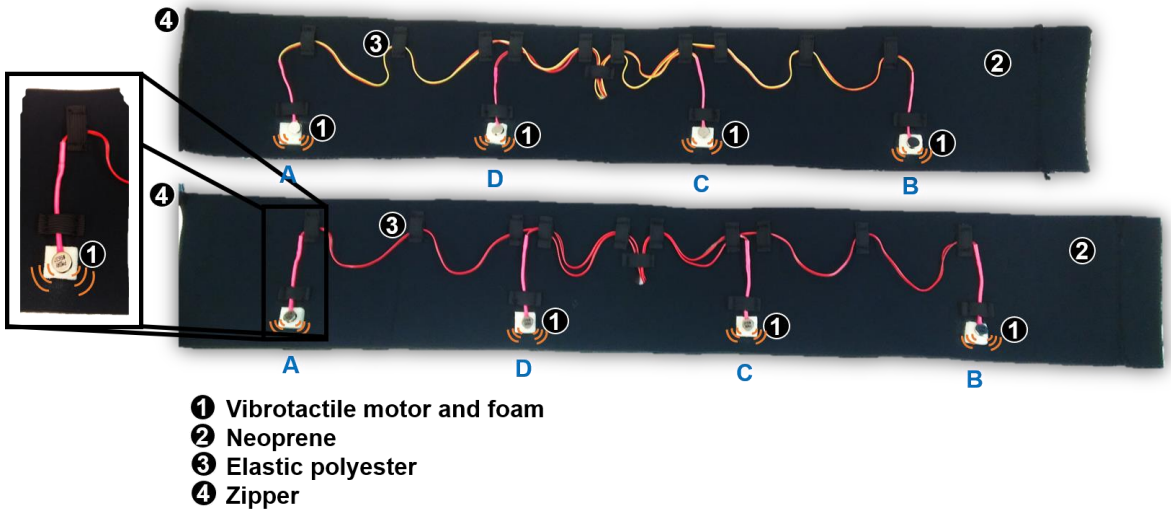
4.4.1 Vibrotactile waistband

The waist is a body area less susceptible to movement during walking [7] and the placement of the vibrotactile motors in this area allows a compact system, since the remaining electronics are allocated on the user's back.

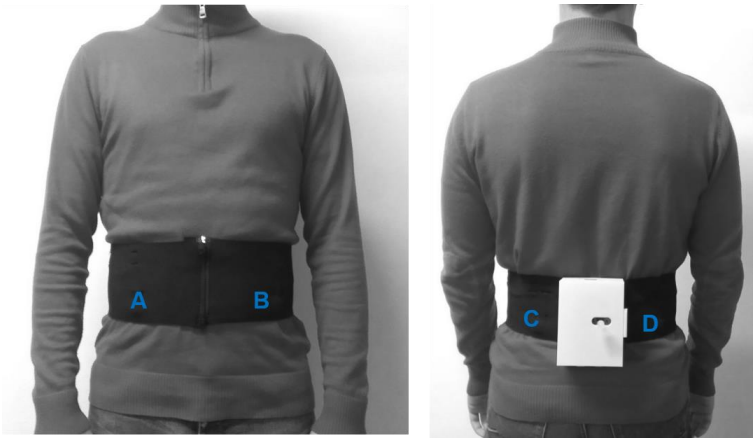
Four ERM motors are placed on the waist through the waistband: two at the front and two at the back with a symmetry between the left and right sides (Figure 4.2). This configuration was chosen because the spatial discrimination is more easily perceived along the transverse axis of the body rather

than the longitudinal axis [35]. Also, placing the ERM motors on the waist's right and left sides seems intuitive to discriminate the biofeedback for the paretic and non-paretic legs, respectively.

Each band has 12 cm height and 3 mm thickness, and the small and large sizes fit in waist's lengths from 66 cm to 83 cm and from 71 cm to 90 cm, respectively. A picture of the vibrotactile waistbands is presented in Figure 4.2.



(A)



(B)

Figure 4.2 - Vibrotactile waistbands: (A) the components (small size above, large size below) and (B) worn by a participant.

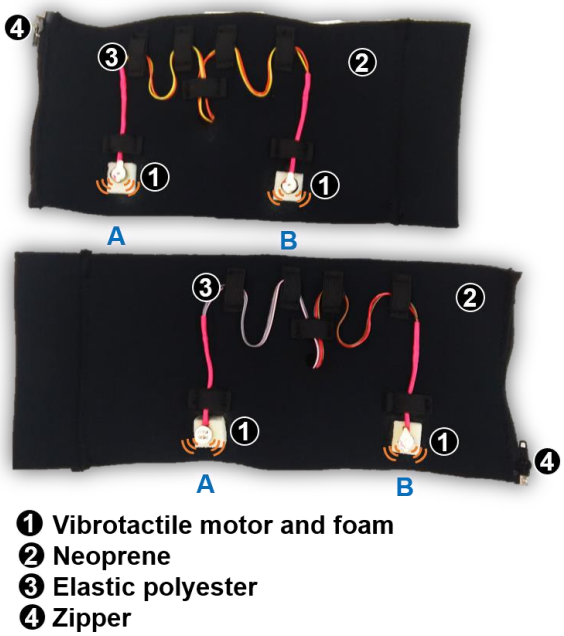
4.4.2 Vibrotactile shank band

The shank is a highly sensitive body area to a vibrotactile stimulus [37], and the placement of the vibrotactile motors in this area can stimulate the principal agonist muscles charged by ankle motion

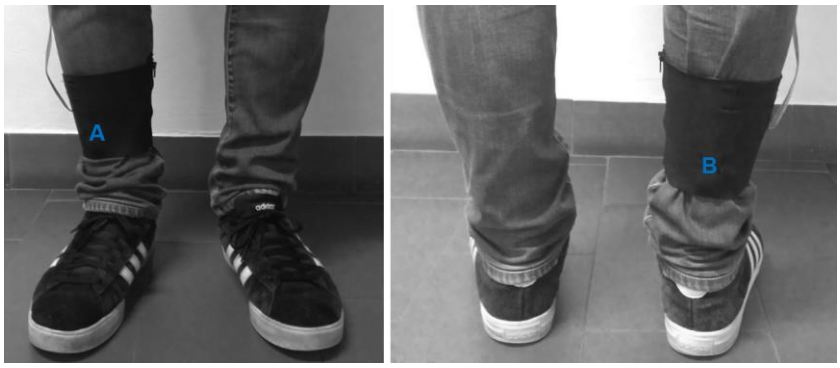
during gait: tibialis anterior and soleus [7], [38], facilitating the active participation of the user. As reported in chapter 2, the shank was successfully used to place the vibrotactile motors [22].

Two ERM motors are placed on the shank through the shank band: one at the front over the tibialis anterior and one at the back over the soleus (Figure 4.3) [7].

Each band has 12 cm height and 3 mm thickness, and the small and the large sizes fit in shank's lengths from 20 cm to 25 cm and from 23 cm to 29 cm, respectively. Figure 4.3 presents the vibrotactile shank bands.



(A)



(B)

Figure 4.3 – Vibrotactile shank bands: (A) the components (small size above, large size below) and (B) worn by a participant.

4.5 Sonorous stimulus's hardware interface

The headphones allow the user to listen to a sound without perturbing other people in opposite to the speaker used in [21]. Moreover, the user can use only one headphone, leaving the other ear completely available to listen to other sounds (for example, advices and motivational statements from the therapist), allowing multitasking. This solution allows to the wearable feature of the BS, in opposite to the screens with audio capability used in [23].

4.6 Visual stimulus's hardware interface

The RGB LED is a small and light component capable of providing a wearable visual stimulus, in opposite to the screens used in [23] and [24]–[27], which can be modulated through variation of the light colour. The chosen LED is diffuse in order to be easily detected in many directions.

The LED is placed on the user's back in order to prevent the user to be disturbed and overwhelmed by the visual stimulus. Moreover, its orientation allows the therapist to detect the visual stimulus from different directions (from the back, left and right sides of the user) (Figure 4.2).

4.7 Conclusions

The developed BS provides sensory, sonorous and visual stimulation through ERM motors, headphones, and an RGB LED, respectively. BS also includes a STM32F4-Discovery board to manage the activation of the stimulators. It can be integrated into the SmartOs or it can be used as a stand-alone module of the SmartOs. Both solutions allow the wearable feature of the BS.

The vibrotactile and sonorous stimuli demand less cognitive effort than the visual stimulus, being used for user-oriented biofeedback strategies. The vibrotactile motors are placed on the user's waist and shank through comfortable and easy to use elastic bands. The headphones provide the sonorous stimulus to the user, allowing multitasking. The visual stimulus is the stimulus chosen for the therapist-oriented biofeedback strategies. The RGB LED is easily understandable to help the therapist to follow the performance of the patients.

The BS's hardware interfaces are centralized in a robust and ergonomic PCB and they are protected by a solid and light 3D printing.

Lastly, the BS's hardware interface follows a user-centered design once it was designed to be light, compact, comfortable, and easy to use, and to allow ambulatory use and multitasking, with low cognitive effort.

5. FOOT-FLOOR CONTACT BIOFEEDBACK STRATEGIES

This chapter describes how the BS's hardware is manipulated in order to teach the orthosis's users to efficiently follow the ankle orthosis movement during trajectory tracking control, boosting the rehabilitation results. The chapter presents the developed user-oriented biofeedback strategies: paretic foot-floor contact biofeedback and non-paretic foot-floor contact biofeedback, justifying all the choices and highlighting its potential features. Also, along with each user-oriented biofeedback strategy, it is explained how the BS's hardware is used to execute the therapist-oriented biofeedback strategies. The chapter ends with the validation protocol and results achieved for each biofeedback strategy. During the validation protocol, the BS was integrated into the SmartOs.

5.1 User-oriented strategies

The foot-floor contact biofeedback strategy aims to teach the user when and how to perform the paretic and non-paretic foot-floor contact. According to a healthy gait trajectory, which the SmartOs-ankle orthosis follows, 60 % of the gait cycle is performed with foot-floor contact – stance phase, and 40 % of the gait cycle is performed without foot-floor contact – swing phase [7]. In this manner, towards gait recovery, the patient needs, firstly, to learn when and how should make the paretic foot-floor contact. Furthermore, a healthy gait is characterized by a symmetric pattern between the legs [7]. Therefore, to achieve a symmetric gait, the user needs to learn when and how should make the non-paretic foot-floor contact in order to the non-paretic leg, also, follows the orthosis's reference trajectory.

For a healthy gait pattern, the foot-floor contact should cover the following steps consecutively: heel-floor contact (heel-strike event), toe-floor contact (flat-foot event), stop the heel-floor contact (heel-off event), and stop the toe-floor contact (toe-off event) [7]. Moreover, both legs should follow a lagged same pattern (when the paretic leg should perform the heel-strike event, the non-paretic leg should perform the heel-off event and vice-versa) [7]. Figure 5.1 shows the SmartOs-ankle orthosis reference trajectory with the both legs' heel-strike, paretic leg's flat-foot, both legs' heel-off and paretic leg's toe-off events identified. The identification of these events followed the gait events description in [7].

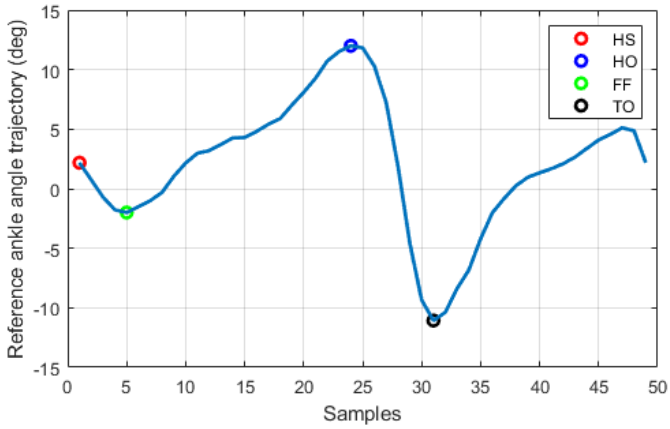


Figure 5.1 – SmartOs AFO reference trajectory (deg). HS – paretic leg's heel-strike / non-paretic leg's heel-off; HO – paretic leg's heel-off / non-paretic leg's heel-strike; FF – paretic leg's flat-foot; TO – paretic leg's toe-off.

In the paretic foot-floor contact biofeedback strategy, according to the SmartOs-ankle orthosis reference trajectory, a stimulus is enabled before the heel-strike event and is disabled before the heel-off event. With this strategy, the user learns when and how long he/she should keep the foot in contact with the floor. On the other hand, in the non-paretic foot-floor contact biofeedback strategy, a stimulus is enabled before both legs' heel-strike event and disabled at the heel-strike event. With this strategy, the user learns to synchronize the non-paretic leg's pattern with the one of the paretic leg, improving the gait symmetry.

The vibrotactile waistband was the chosen stimulator for this strategy since it provides an intuitive biofeedback for both paretic and non-paretic foot-floor contact. For the paretic foot (right foot because the SmartOs-ankle orthosis only fits on the right limb), only the vibrotactile motors placed on the right side of the waist band are enabled; for the non-paretic foot, the vibrotactile motors placed on the right and left sides of the waist band are enabled before the heel-strike event of the right and left leg, respectively. Figure 5.2 shows a schematic of these strategies.

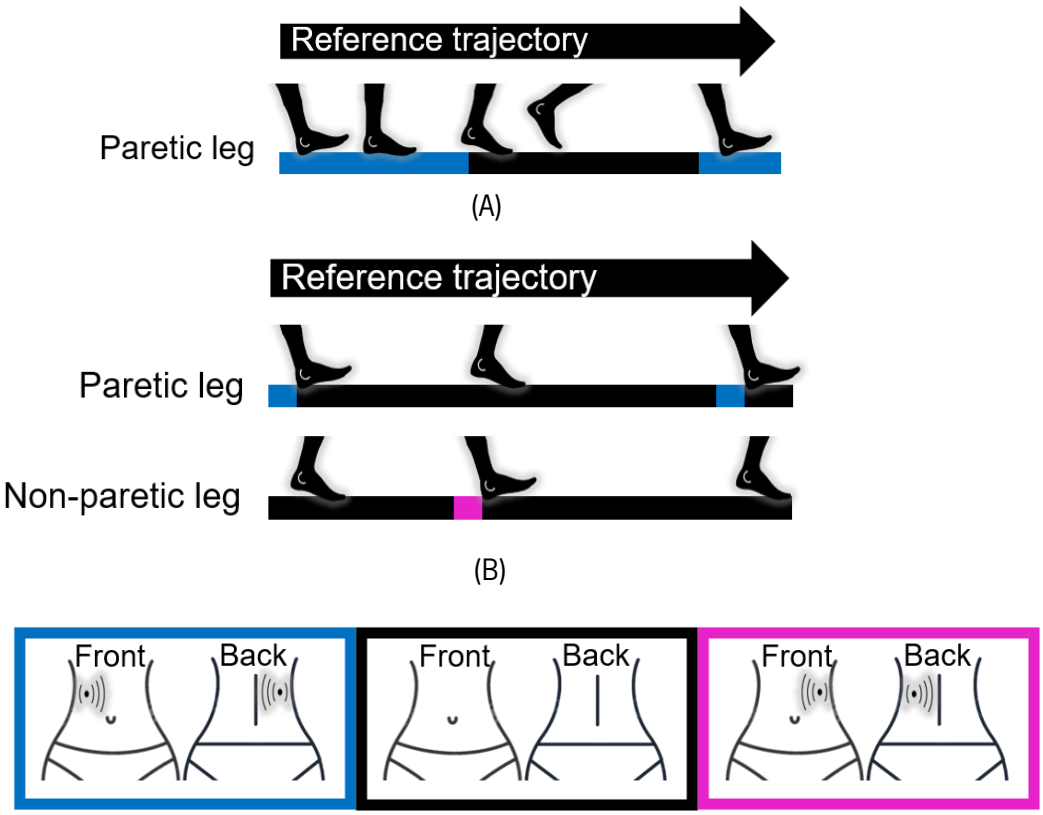


Figure 5.2 - Schematic of the (A) paretic and (B) non-paretic foot-floor contact user-oriented biofeedback strategies.

Since the user should perform the heel-strike and heel-off events according to the orthosis's reference trajectory, the stimulus is enabled/disabled before the events to compensate the time that the user takes to detect/stop detecting the stimulus (reaction time). The ERM motors are enabled/disabled 470 ms before the events. This reaction time was set through empiric analysis of the walking performance of a healthy participant walking with the orthosis and the BS (see details in Appendix III). Once enabled, the vibrotactile stimulus was set to 200 Hz and 1.8 G. As reported in the chapter 2, this frequency was successfully used to enable vibrotactile motors placed on the shank of post-stroke patients [22]. However, the waist is a body area less tactile sensitive than the shank [37]. Therefore, two ERM motors are activated simultaneously in order to facilitate the user's perception of the vibrotactile stimulus, which is highly important for post-stroke patients because they lose the sense of touch [5].

Overall, during paretic foot-floor contact biofeedback, the users should perform the heel-strike and heel-off when they detect and stop detecting the vibration from the waist's right side, respectively. During the non-paretic foot-floor contact biofeedback, the users should perform the right and left leg's heel-strike when they detect the vibration of the right and left side of the waist, respectively. Therefore, the users only need to distinguish the on and off state of the stimulus, which allows the system to be easily understandable, following a user-centered design. Additionally, since the flat-foot and toe-off should be

performed closely to the heel-strike and heel-off events (Figure 5.1), respectively, the user is instructed to perform these events immediately after the heel-strike and heel-off events, respectively.

The on/off state of the vibrotactile stimulus is transferred from the LLOS to the CCU to be locally storage, enabling a posterior analysis at the end of the therapy in order to validate the correct functioning of the BS. Figure 5.3 shows the state of the vibrotactile stimulus during trials running the paretic and the non-paretic foot-floor contact biofeedback strategies.

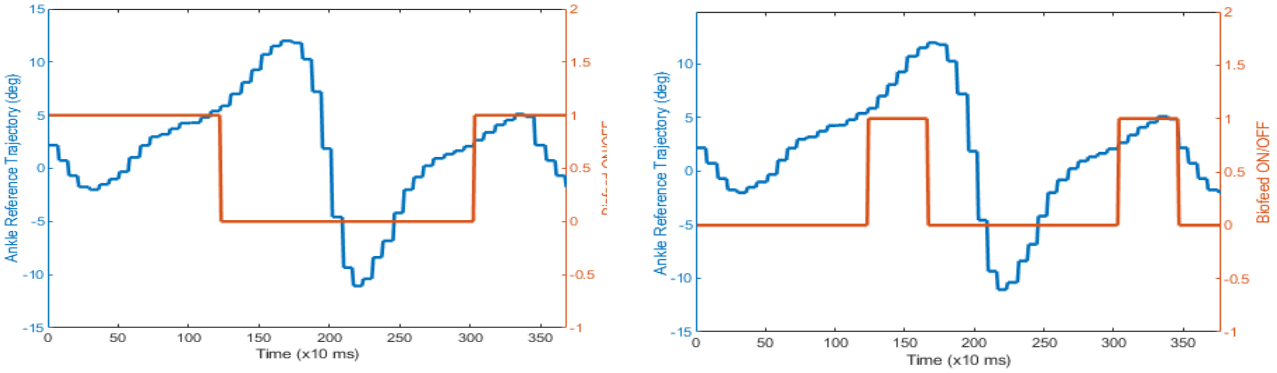


Figure 5.3 – State of the vibrotactile stimulus (on=1/off=0), Biofeed, and the SmartOs-ankle orthosis reference trajectory (deg), Ankle Reference Trajectory, during the (A) paretic foot-floor biofeedback; (B) non-paretic foot-floor biofeedback. In the first strategy, the vibrotactile stimulus is enabled and disabled 470 ms before the orthosis's heel-strike and heel-off, respectively. In the second strategy, the vibrotactile stimulus is enabled 470 ms before the orthosis's heel-strike and heel-off (it should correspond with the left leg's heel-strike) and disabled at these events, respectively.

5.2 Therapist-oriented strategies

Since the therapist can easily follow the execution of the user's foot-floor contact through visual inspection, the visual stimulus, in this strategy, is enabled to inform the therapist what the user should do. The therapist can see a blue and pink light when the right and left sides of the waist vibrate, respectively. Therefore, during the paretic foot-floor contact biofeedback strategy, when the therapist sees the blue light appearing means that the user should perform the heel-strike followed by the flat-foot (Figure 5.4A). When the therapist sees the blue light disappearing means that the user should perform the heel-off followed by the toe-off (Figure 5.4A). During the non-paretic foot-floor contact biofeedback, when the therapist sees the blue and pink lights mean that the user should perform the right leg and left leg's heel-strike, respectively (Figure 5.4B). Thus, the therapist should motivate and advice the patients, accordingly.

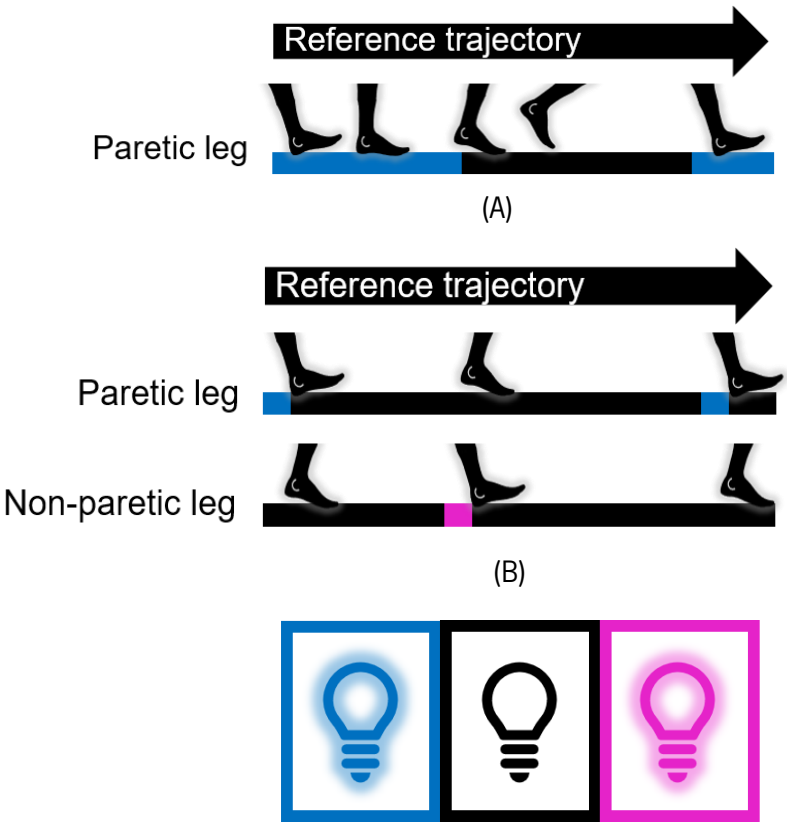


Figure 5.4 - Schematic of the (A) paretic and (B) non-paretic foot-floor contact therapist-oriented biofeedback strategies.

5.3 Validation protocol

5.3.1 Participants

Six healthy participants, four belonging to the experimental group (age: 25.0 ± 1.4 years, height: 1.69 ± 0.13 m, body mass: 65 ± 12 kg) and two belonging to the control group (age: 25 ± 0 years, height: 1.78 ± 0.03 m, body mass: 72 ± 5 kg), were recruited to perform the validation protocol of the paretic and non-paretic foot-floor contact biofeedback strategies (Table 5.1). All the participants are already familiarized with the SmartOs-ankle orthosis trajectory tracking control. Participants signed a written informed consent to participate in the studies presented in this dissertation.

Table 5.1 - Age (years), height (m), body mass (kg) and group (experimental and control) of each participant

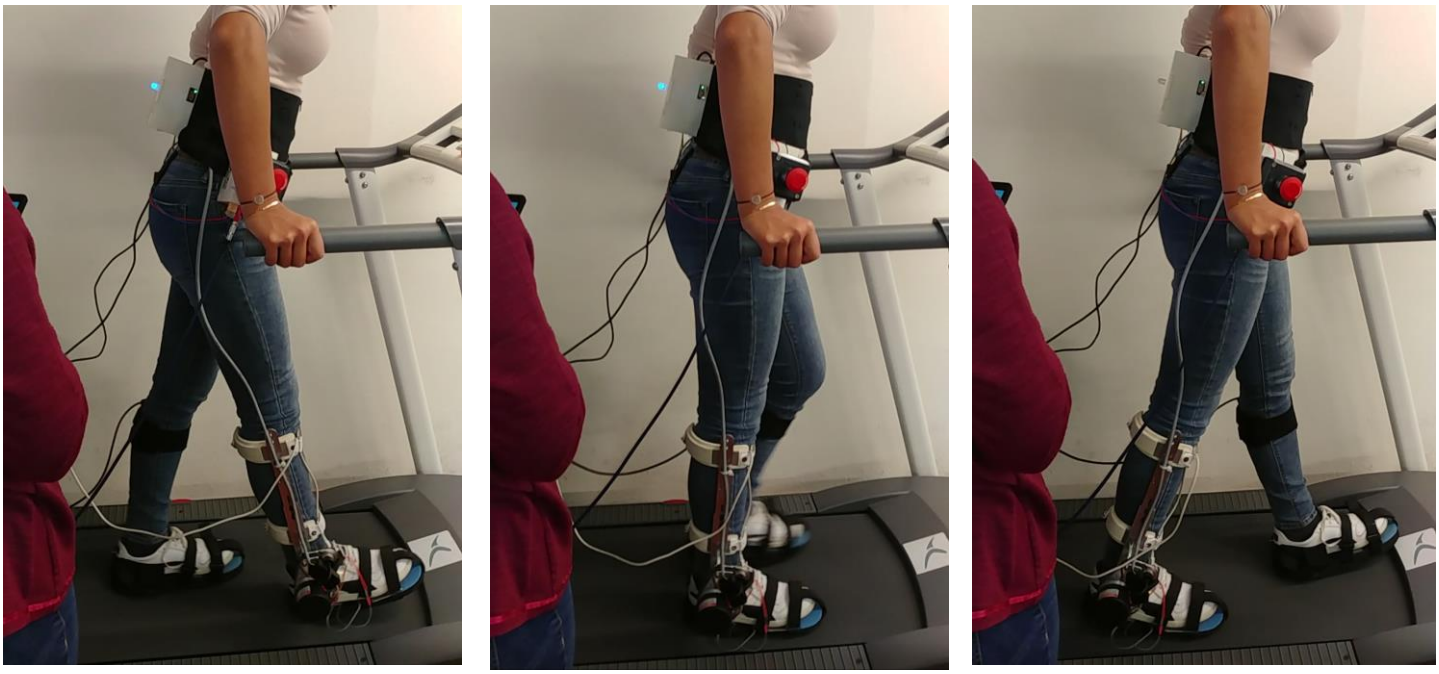
	Age (years)	Height (m)	Body mass (kg)	Group
Participant 1	27	1.62	53	Experimental
Participant 2	25	1.82	77	Experimental
Participant 3	25	1.82	76	Experimental
Participant 4	23	1.51	52	Experimental
Participant 5	25	1.75	76	Control
Participant 6	25	1.81	67	Control

5.3.2 Experimental protocol

For a proof of the concept, one training session was performed with the paretic foot-floor contact biofeedback strategy followed by one training session with the non-paretic foot-floor contact biofeedback strategy. This order was chosen because the users need to learn, firstly, when and how to make the paretic followed by the non-paretic foot-floor contact, since the efficacy of one strategy may depends on the efficacy of the previous one.

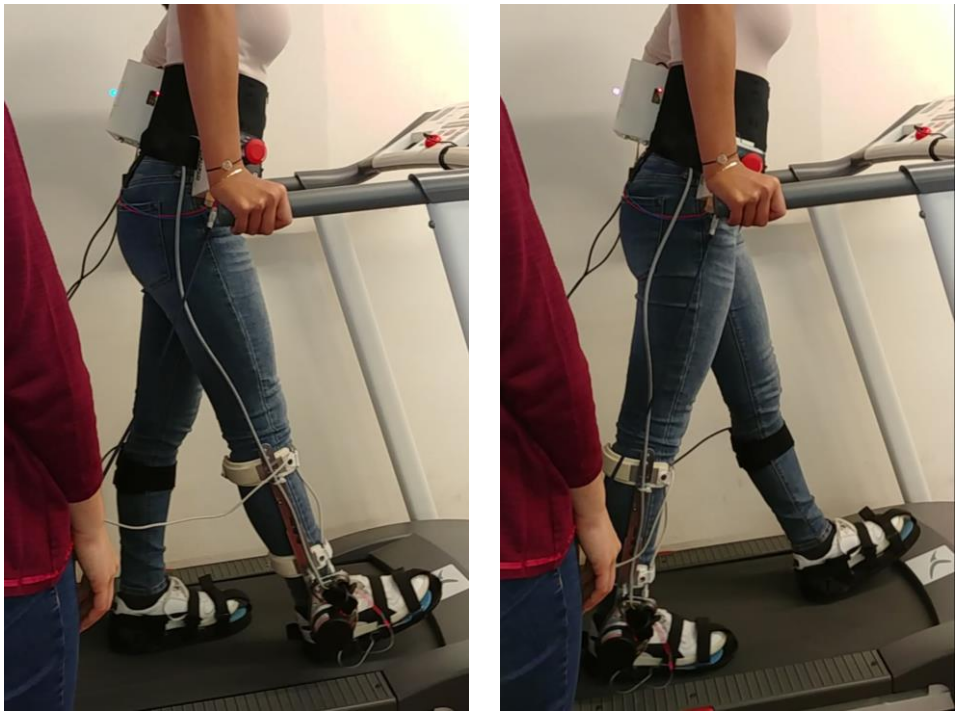
For the experimental group, each training session comprises four procedures, as follows: three trials only with the orthosis (procedure 1), one familiarization trial with the BS-based orthosis therapy (procedure 2), three trials with the BS-based orthosis therapy (procedure 3), one retention trial (procedure 4). Each trial lasted 1 min. In the four procedures, the orthosis assisted through the trajectory tracking control at 1.0 km/h. The walking speed of 1.0 km/h was chosen because it is the lowest treadmill's speed, reducing the cognitive effort during each gait cycle, as well as it is the closest gait speed of a stroke survivor walking on the treadmill. The control group performed all the procedures only with the orthosis (without the BS).

Before the procedures, the participant wore the BS, orthosis and GaitShoe. The GaitShoe provides the non-paretic foot-floor contact through the embedded FSRs. During the procedure 1, the participants were instructed to follow the orthosis movement without the BS cues. For the procedures 2 and 3, the participants were instructed to follow the orthosis movement according to the feedback of the BS cues. After 2 min of the end of the procedure 3, the retention trial (procedure 4) was performed where the user was instructed to follow the orthosis movement, without BS cues, trying to repeat the pattern learned during the previous procedure. Figures 5.5 and 5.6 show pictures of the participant 1 during the training with the paretic and non-paretic foot-floor contact biofeedback followed by the therapist.



(A) (B) (C)

Figure 5.5 - Paretic foot-floor contact biofeedback training of the participant 1 followed by the therapist. (A) The vibrotactile stimulus from waist starts (blue light) and the participant should perform the heel-floor contact; (B) The vibrotactile stimulus from waist remains (blue light) until the orthosis's heel off and the participant should remain the foot-floor contact; (C) The vibrotactile stimulus from waist stops (no light) and the participant should stop the heel-floor contact.



(A) (B)

Figure 5.6 - Non-paretic foot-floor contact biofeedback training of the participant 1 followed by the therapist. (A) The vibrotactile stimulus from waist's right side starts (blue light) and the participant should perform the right leg's heel-strike; (B) The vibrotactile stimulus from waist's left side starts (pink light) and the participant should perform the left leg's heel-strike.

5.3.3 Data Collection and Analysis

Data from the orthosis's embedded heel FSR and the reference trajectory were collected in the paretic foot-floor contact biofeedback strategy. Data from the heel FSR placed on the left foot (using the GaitShoe and WML), from the orthosis's embedded heel FSR and the reference trajectory were collected in the non-paretic foot-floor contact biofeedback. Data collection was performed at 100 Hz. Note that no data were acquired during the familiarization procedure. The comments of the participants from the experimental group and the therapist were registered after the use of each biofeedback strategy.

For validating the paretic foot-floor contact biofeedback strategy, the average module delay between the orthosis's and user's heel-strike, as a percentage of the gait cycle, was calculated. The same procedure was executed for the heel-off. The orthosis's embedded heel FSR and reference trajectory provide the user's and orthosis's events, respectively. The first and last three gait cycles of each trial were discarded from the analysis.

Aiming the validation of the non-paretic foot-floor contact biofeedback strategy, the average module delay between the orthosis's heel-off and user's left leg's heel-strike, as a percentage of the gait cycle, was calculated. The same procedure was executed between the orthosis's and user's heel-strike. The orthosis's embedded heel FSR, the heel FSR from GaitShoe and the reference trajectory provide the user's right leg, left leg and orthosis's events, respectively. The first and last three gait cycles of each trial were not analysed.

5.4 Results and Discussion

5.4.1 Paretic foot-floor contact biofeedback

During the execution of the validation protocol with the paretic foot-floor contact biofeedback strategy, the participants follow cyclically the instructed pattern: heel-floor contact, toe-floor contact, stopped the heel-floor contact and stopped the toe-floor contact, as illustrated in Figure 5.5.

Figure 5.7 shows the average module delay between the orthosis's and user's heel-strike and the average module delay between the orthosis's and user's heel-off before, during and after the use of the BS. These results were collected from the participants 1, 2, 3 and 4, belonging to the experimental group.

Figure 5.8 shows the average module delay between the orthosis's and user's heel-strike and the average module delay between the orthosis's and user's heel-off before, during and after the second round of three trials only with the orthosis (procedure 3) by the participants 5 and 6, belonging to the control group.

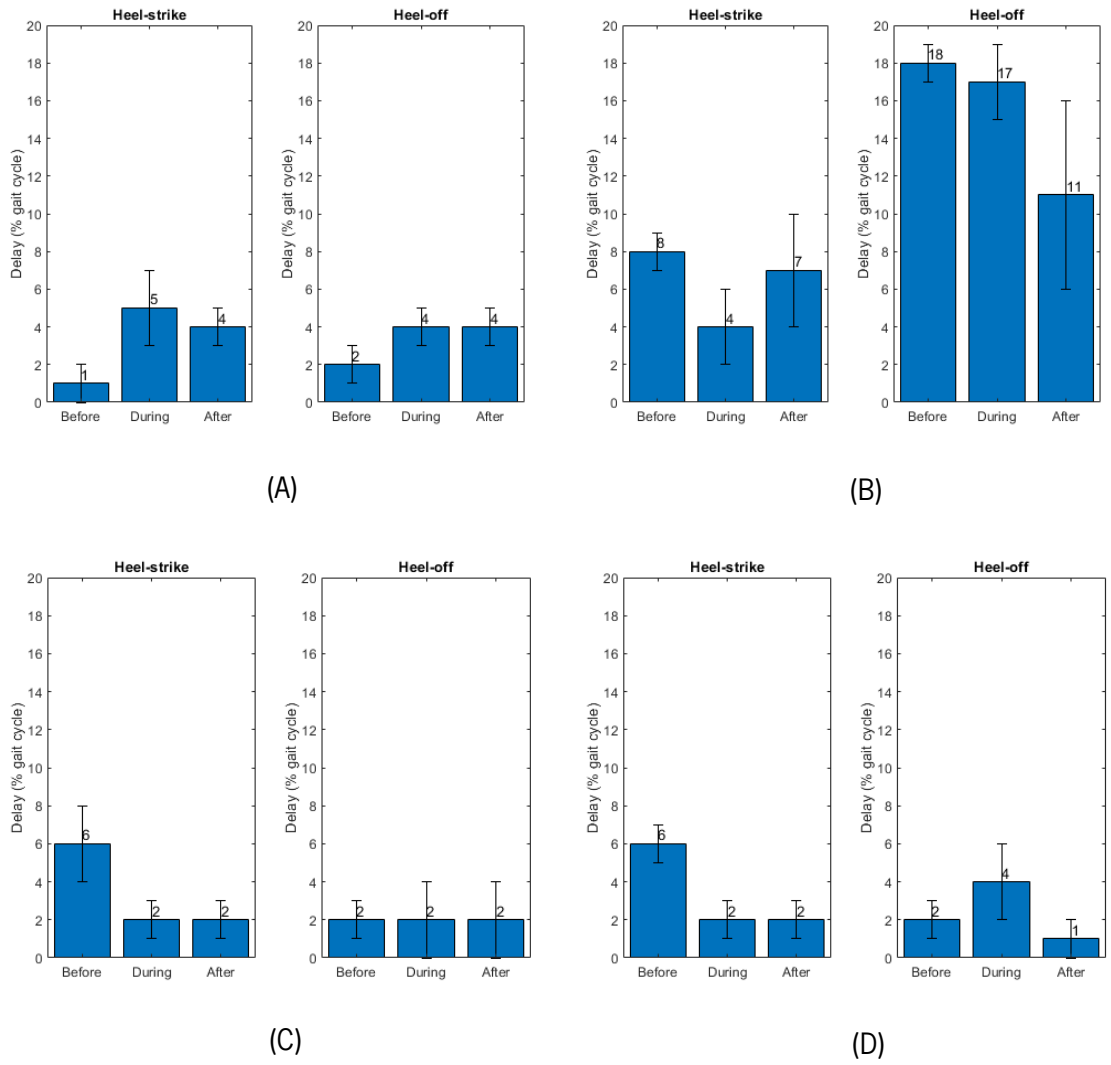


Figure 5.7 - Average module delay (% gait cycle) between orthosis's and user's heel-strike and heel-off before, during and after the use of the paretic foot-floor contact biofeedback. These parameters are presented for the participant (A) 1, (B), 2, (C), 3 and (D) 4, belonging to the experimental group.

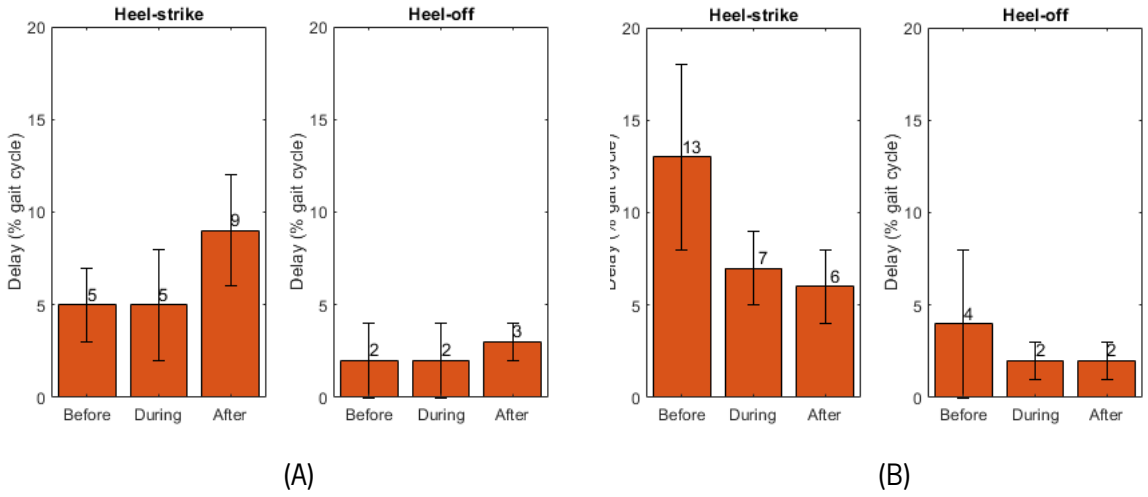


Figure 5.8 - Average module delay (% gait cycle) between orthosis's and user's heel-strike and heel-off before, during and after the second round of 3 trials only with the orthosis. These parameters are presented for the participant (A) 4 and (B) 5, belonging to the control group.

Table 5.2 presents some comments of the participants after the use of the BS.

Table 5.2 - Participants' comments after the use of the paretic foot-floor contact biofeedback

Participant 1	Participant 2	Participant 3	Participant 4
• The vibrotactile cues are perceptible, and they are not uncomfortable; • She felt that the orthosis's boosted her movement towards swing phase and, then, towards flat-foot.	• This strategy is easily understandable, but it is very important to be calm and concentrated; • She felt that with biofeedback she is not pushing the orthosis so hard during walking.	• It is a little difficult to think in the heel-strike and heel-off in the same gait cycle; • He thinks that the biofeedback helped him to be more synchronous with the orthosis's movement.	• He felt more confidence to use the orthosis, mainly to execute the first foot-floor contact; • He felt that needs more training to reduce the cognitive effort.

As can be observed through Figure 5.7, most of the participants decreased the average module heel-strike delay. Thus, the paretic foot-floor contact biofeedback strategy may be applied to teach the orthosis's users when the heel-floor contact should be made according to the orthosis's reference trajectory. The low decrement may be related to the healthy motor ability of the participants, their high familiarity with the orthosis and the short biofeedback training period. The slightly increased delay, obtained for the participant 1, indicates a need to develop a more effective strategy to define the user's reaction time. The strategy should consider the stimulus, the action that the participants should execute in response to the stimulus and their mental and physical fatigue during that period. On the other hand, the strategy can be adjusted to be independent of the user's reaction time. For example, the biofeedback could be enabled if the user fails these events, and the users should adapt their pattern accordingly in real-time.

The results of the retention test (after the use of the BS), presented in Figure 5.7, show that the participants 3 and 4 kept the average module heel-strike delay after the use of the BS. Thus, they learned the trained gait pattern with the biofeedback. However, the slightly decreased result of the participant 2, regarding the average module delay obtained before the use of the BS, shows that she needs more training to be able to perform the trained gait pattern autonomously. The retention test of the participant 1 was not considered for analysis since she did not improve their gait pattern with the biofeedback.

In the control group, it was noticed that the participant 5 did not vary the average module delay until the last trained trial in which he increased this parameter possibly due to the lack of concentration (Figure 5.8). On the other hand, the participant 6 decreased progressively the average module heel-strike delay (Figure 5.8).

Relatively to the heel-off event (Figure 5.7), as expected, the participant 1 slightly increased the average module delay during the use of the biofeedback once it was used the same reaction as for heel-strike. However, the participant 4 also increased this parameter which indicates a need to study if there is a difference between the reaction time to percept a stimulus and to stop the perception. Although, this increase can also be related to the commented cognitive effort (Table 5.2) and, consequently, the need for a longer training period. On the other hand, the participant 2 slightly decreased whereas the participant 3 kept the average module heel-off delay. These slight variations can be due to the lack of biofeedback training. In the case of the participant 3, it can be due, also, with his healthy motor ability and his high familiarity with the orthosis. Overall, there is a need to perform a longer validation protocol in order to prove the effectiveness of the paretic foot-floor contact biofeedback strategy to teach the orthosis's users to stop the heel-floor contact according the orthosis's reference trajectory.

The retention tests of the participants 1, 3 and 4 were not considered for analysis since they did not improve their gait pattern with the biofeedback. On the other hand, after the use of the BS, the participant 2 decrease 7 % of the average module delay in comparison with the biofeedback training, indicating that the trials before the use of the BS were not enough to evaluate the average module delay of the participant in that condition (Figure 5.7).

Relatively to the control group, it was noticed that the participant 5 did not vary the average module delay until the last trained trial in which he slightly increased this parameter possibly due to the lack of concentration (Figure 5.8). On the other hand, the participant 6 slightly decreased the average module heel-off delay between the first and the second round of three trials (Figure 5.8).

From Table 5.2, participant 1 commented that the stimulus is easily perceived, and it was considered comfortable. The participant 2 commented that the strategy is easily understandable, but it is important to be concentrated indicating that the it involves a considerable cognitive effort, as mentioned by the participant 4. The participant 3 mentioned the difficulty that he felt to think in the heel-strike and heel-off events in the same gait cycle, indicating, also, the considerable cognitive effort that the strategy demands. The cognitive effort can be decreased, improving the biofeedback strategy to teach how and when to perform the paretic foot-floor contact and, then, how and when to stop the paretic foot-floor contact. Moreover, the participant 4 revealed that he is more confident to use the orthosis, proving the promising impact of the biofeedback as a complementary tool in orthotic-based gait rehabilitation. Furthermore, in concordance with the resulted average module delay, the participant 1 felt the orthosis boosting her movement, indicating that she is not synchronized with the orthosis. On the other hand, the

participants 2 felt that the orthosis is not pushing her so hard, indicating that she is more synchronized with the orthosis, as mentioned by the participant 3.

The therapist commented that the RGB LED should be closer to the paretic limb so that the visual stimulus and the paretic limb can be observed in the same field of vision. Regardless of that, the visual stimulus is easily understandable, and it provides the needed information once it is difficult to detect the orthosis's events only by visual inspection of its movement.

5.4.2 Non-paretic foot-floor contact biofeedback

Figure 5.9 shows results of experimental group, namely the average module delay between the orthosis's and user's heel-strike, and the average module delay between the orthosis's heel-off and the user's left leg's heel-strike before, during and after the use of the BS.

Figure 5.10 shows findings of control group, including the average module delay between the orthosis's and user's heel-strike and the average module delay between the orthosis's heel-off and the user's left leg's heel-strike before, during and after the second round of three trials only with the orthosis.

Table 5.3 presents some comments of the participants after the use of the BS.

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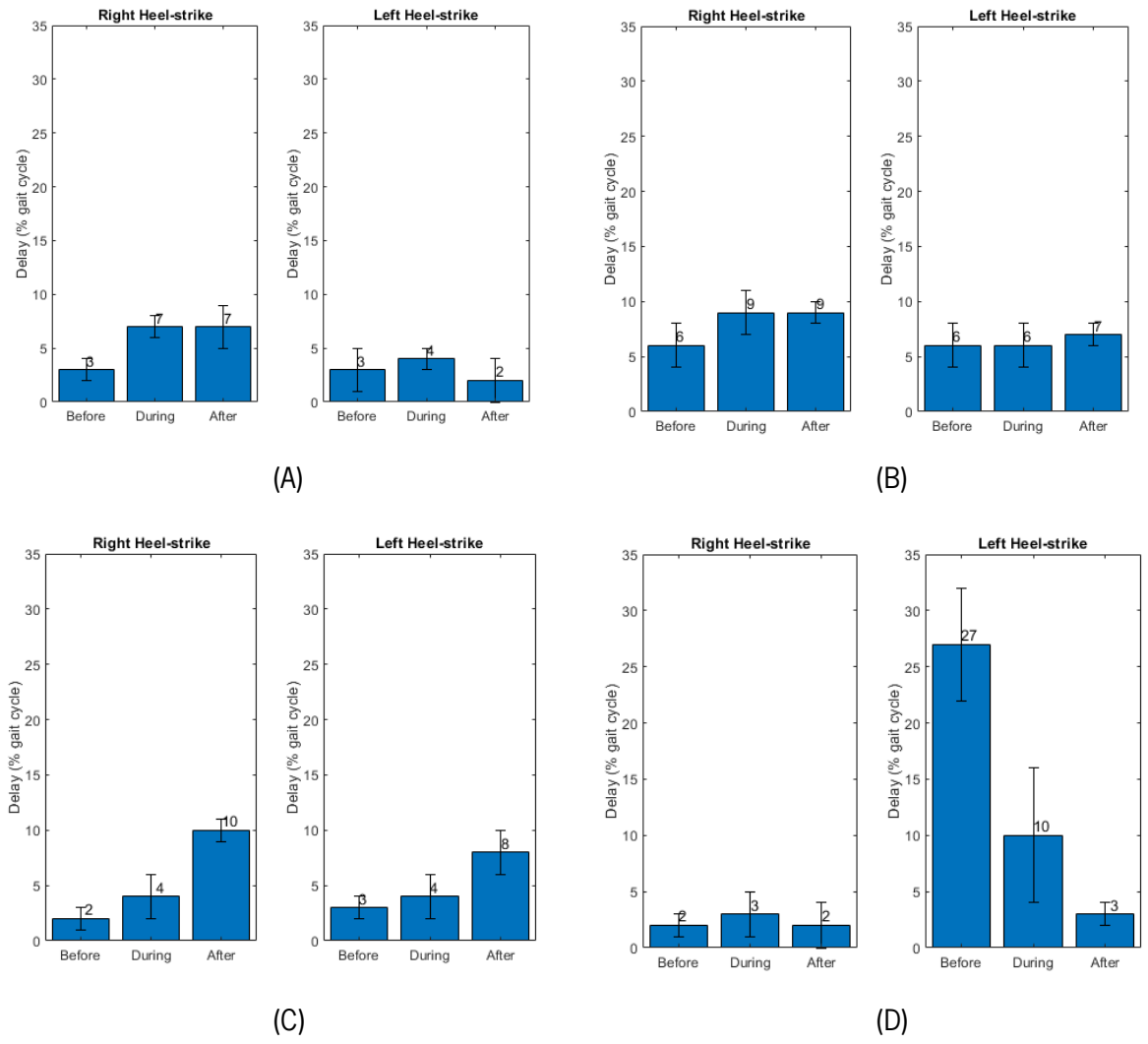


Figure 5.9 - Average module delay (% gait cycle) between orthosis's heel-strike and heel-off, and user's right leg's and left leg's heel-strike, respectively, before, during and after the use of the non-paretic foot-floor contact biofeedback. These parameters are presented for the participant (A) 1, (B), 2, (C), 3 and (D) 4, belonging to the experimental group.

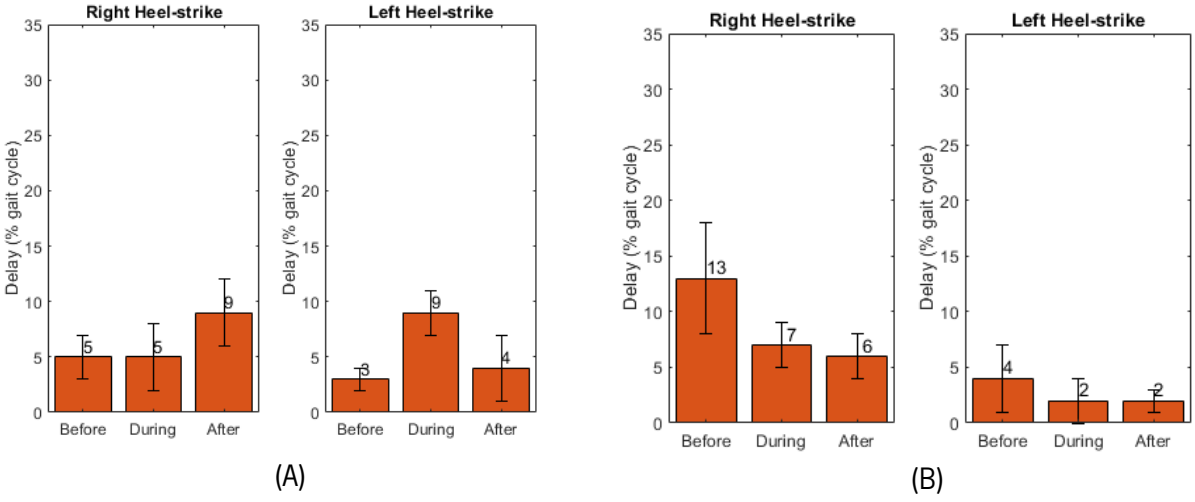


Figure 5.10 - Average module delay (% gait cycle) between orthosis's heel-strike and heel-off, and user's right leg's and left leg's heel-strike, respectively, before, during and after the second round of 3 trials with the orthosis. These parameters are presented for the participant (A) 4 and (B) 5, belonging to the control group.

Table 5.3 - Participants' comments after the use of the non-paretic foot-floor contact biofeedback

Participant 1	Participant 2	Participant 3	Participant 4
• This strategy is intuitive, and it involves low cognitive effort; • She tried to think in more than what it was instructed (right leg's heel-off) and it deconcentrated her from biofeedback. Because of that, she thinks that needs more training.	• The biofeedback of each leg is intuitive to distinguish; • She had difficulty thinking about the right leg's heel-strike because she, involuntary, filled in her mind thinking in the left leg's heel-strike and right leg's heel-off.	• It is easier to think in the execution of the same event (both legs' heel-strike) in comparison with different events (heel-strike and heel-off); • He felt that the orthosis's heel-off disturbed him from the biofeedback. So, he feels that needs more training.	• This strategy is not cognitively difficult; • He felt that the biofeedback helped him to walk more symmetric because he does not feel the need to hold his hands on the treadmill so tightly to keep balance.

By analysing Figure 5.9, all the participants increased the average right leg's heel-strike delay in the non-paretic foot-floor biofeedback strategy. This result can be explained by the commented avoidance from the biofeedback due to the orthosis's heel-off (Table 5.3). Since the orthosis's heel-off takes the user's attention, it is too much cognitive effort for the users to think about both legs' heel-strike and the right's leg heel-off. In this manner, a longer training period should be performed to study the user's adaptability to the biofeedback. Also, it can be interesting to use this biofeedback strategy during passive control to avoid the disturbances caused by the autonomous orthosis's movement.

The retention tests were not considered for analysis since the participants did not improve their gait pattern with the biofeedback.

Despite this, the participant 4 achieved a 17 % left leg's heel-strike delay decrease during the use of the BS (Figure 5.9). This successful achievement can be related to the high need of the biofeedback in comparison to the remain participants since this participant had a higher average module delay before the use of the biofeedback (27 %) (Figure 5.9). Thus, it indicates that the BS may have better results with participants who have gait injuries. Along with this, it is important to perform a new validation protocol which should evolve participants who had no familiarity with the orthosis. Since the participant 4 slightly varied the average module right leg's heel-strike delay (Figure 5.9), it can be concluded that the non-paretic foot-floor biofeedback strategy helped him to achieve a more symmetric gait. However, it is necessary to perform a new validation with a large group of participants to assess this hypothesis.

The retention tests of the participants 1, 2 and 3 were not considered for analysis since they did not improve their gait pattern with the biofeedback. On the other hand, after the use of the BS, the participant 4 decreased 7 % of the average module delay regarding the biofeedback training, indicating

that the trials before the use of the BS were not enough to evaluate the average delay of the participant in that condition (Figure 5.8).

Relatively to the control group, it was noticed that the participant 5 increased the average module left leg's heel-strike delay between the first and the second round of three trials and, then, decreased. On the other hand, the participant 6 slightly decreased the average module left leg's heel-strike delay between the first and the second round of three trials.

Table 5.3 shows that the participant 1 commented that the non-paretic foot-floor contact biofeedback strategy is intuitive, involving low cognitive effort, as mentioned by the participant 4. The participant 2 commented that the biofeedback of each leg is easily distinguished, supporting, also, the intuitive feature of the strategy. The participant 3 mentioned that it is easier to think in the same event than different events, indicating, also, the low cognitive effort of the strategy. In this manner, the strategy should be improved using the heel-off event to the detriment of heel-strike, reducing the additional cognitive effort caused by the orthosis's heel-off, mentioned by all the participants. Thus, the patients will learn when they should perform the paretic and non-paretic heel-off, improving the gait symmetry. Moreover, the participant 4 was the only who commented that he felt an improvement in the gait symmetry once he did not feel the need to hold his hands on the treadmill so tightly to keep balance.

The therapist noted that her commentaries about the previous strategy are equally verified in this strategy.

5.5 Conclusions

The results of the foot-floor contact biofeedback strategies appointed to a need to develop a more effective strategy to define the user's reaction time, considering the participants' mental and physical fatigue during the use of the biofeedback. Also, it should be studied if there is a difference in the reaction time to percept the stimulus at the initial and final perception moment.

Additionally, both strategies may be adjusted to be independent of the user's reaction time, giving the biofeedback based on the user's performance.

In the paretic foot-floor contact biofeedback strategy, the patients should learn how and when they should perform the foot-floor contact and, then, how and when they should stop it, decreasing the cognitive effort.

It can be interesting to use these biofeedback strategies during passive control to avoid the disturbances caused by the autonomous orthosis's movement. On the other hand, in the non-paretic foot-floor contact biofeedback strategy, the patients should learn when they should perform the paretic and

non-paretic leg's heel-off to the detriment of the heel-strike to reduce the additional cognitive effort caused by orthosis's autonomous movement.

6. INTERACTION TORQUE-BASED BIOFEEDBACK STRATEGIES

This chapter describes how the BS's hardware is manipulated in order to teach the orthosis's users to efficiently follow the ankle orthosis movement during trajectory tracking control, boosting the rehabilitation results. The chapter presents the developed interaction torque-based user-oriented biofeedback strategies: joint motion biofeedback and user participation biofeedback, justifying all the choices and highlighting its potential features. Also, along with each user-oriented biofeedback strategy, it is explained how the BS's hardware is used to execute the therapist-oriented biofeedback strategies. The chapter ends with the validation protocol and results achieved for each biofeedback strategy. During the validation protocol, the BS was integrated into the SmartOs.

6.1 Joint motion biofeedback strategy

The joint motion biofeedback strategy aims to teach the user the direction of movement along the gait cycle, according the SmartOs-ankle orthosis reference trajectory. There are two ankle movements performed along the gait cycle: the ankle rotation towards the increase of the reference trajectory – dorsiflexion; and, the ankle rotation towards the decrease of reference trajectory – plantar flexion [7]. These two movements occur consecutively during the gait cycle, as illustrates Figure 6.1. In this manner, when the orthosis performs dorsiflexion, the user should perform as well and the same should happen regarding plantar flexion.

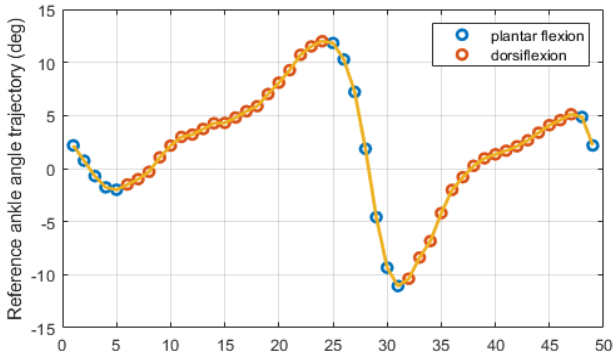


Figure 6.1 – SmartOs-ankle orthosis reference trajectory (deg) with identification of the samples regarding plantar flexion (blue circles) and dorsiflexion (orange circles).

6.1.1 User-oriented strategy

When the user does not apply a force to the orthosis, there is a baseline interaction torque from -2 Nm to 2 Nm, as empirically observed (Appendix I). The interaction torque increases and decreases concerning the orthosis's baseline interaction torque when the user applies a force towards the decrease and increase of the orthosis's reference trajectory, respectively (Appendix I). The interaction torque is equal to the baseline when the user does not apply a force on the orthosis, indicating that the user is synchronized with the orthosis's healthy reference trajectory (Appendix I).

Therefore, the comparison between the interaction torque and the reference trajectory allows concluding if the user performs the ankle rotation according to the orthosis's reference trajectory, as follows. When the reference trajectory increases, the interaction torque should decrease regarding the baseline or be equal to it; when the reference trajectory decreases, the interaction torque should increase concerning the baseline or be equal to it. If these situations do not happen, it is concluded that the user is applying a counterforce to the orthosis's reference movement.

According to the above information, when the orthosis's reference trajectory increases, a stimulus is activated if the interaction torque is higher than 2 Nm. On the other hand, when the orthosis's reference trajectory decreases, a stimulus is activated if the interaction torque is lower than -2 Nm. The stimulus remains until the condition stops.

A sonorous stimulus was chosen for this strategy to reduce the system's cognitive effort if more than one biofeedback strategy is used simultaneously [23]. The chosen sonorous stimulus should stimulate a neutral feeling to the users and, consequently, do not overwhelm them. Moreover, the volume was adjusted to allow the patient to easily ear external sounds, like the therapist's motivational statements and advices, allowing multitasking.

Figure 6.2 shows a schematic of the joint motion user-oriented biofeedback strategy.

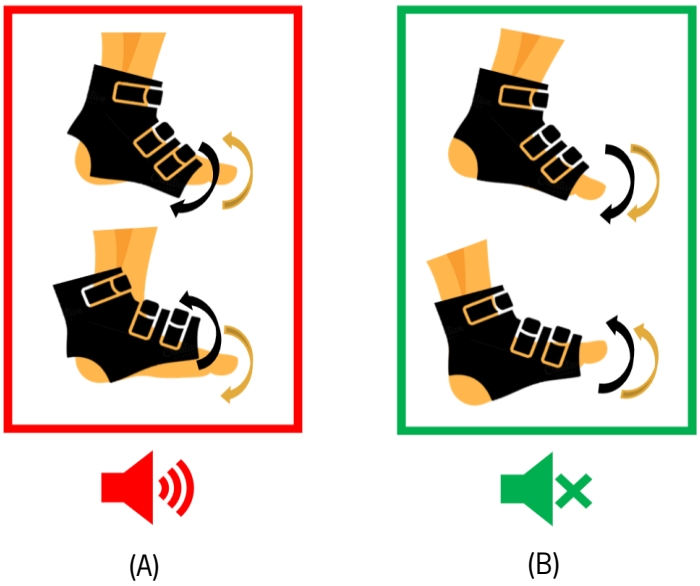


Figure 6.2 - Schematic of the joint motion user-oriented biofeedback strategy. User is (A) against and (B) according the orthosis's movement. The black and yellow arrows represent the orthosis's and user's movement, respectively.

The sonorous stimulus can be activated during one or more of the indicated actuation phases in Figure 6.3. Comparing the Figure 6.1 with Figure 6.3, the phases 1 and 3 correspond to the two orthosis's dorsiflexion phases, and the phases 2 and 4 correspond to the two orthosis's plantar flexion phases. In this manner, a pre-training trial should be acquired only with the orthosis (without the biofeedback) in order to conclude about the phases in which the user has the lowest performance. If the user has a considerable low performance in more than one phase, it is more effective to recovery one phase at a time in order to not overwhelm the patient.

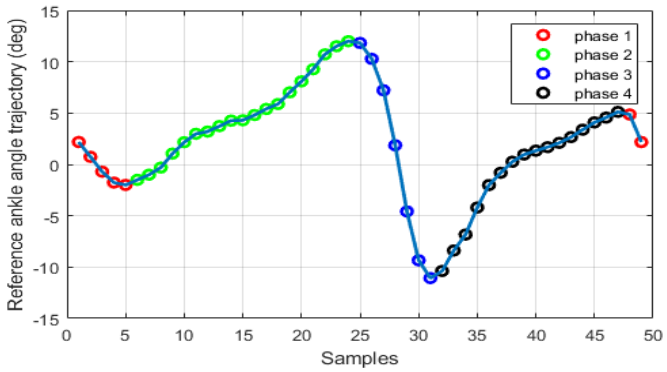


Figure 6.3 – SmartOs reference trajectory (deg) divided in the four actuation phases (phase 1, phase 2, phase 3, phase 4).

Overall, during joint motion biofeedback, the users should pay attention to the orthosis's movement and try to move in accordance actively. When the users ear the sonorous stimulus, they should change the direction of the applied force. As can be perceived, the user only needs to distinguish the on and off state of the sonorous stimulus, which turns the BS easily understandable, following a user-centered design.

The on/off state of the sonorous stimulus is transferred from the LLOS to the CCU, where is locally storage for posterior analysis at the end of the therapy in order to validate the correct functioning of the BS. Figure 6.4 shows the state of the sonorous stimulus for trial running the joint motion biofeedback strategy on the actuation phase 3.

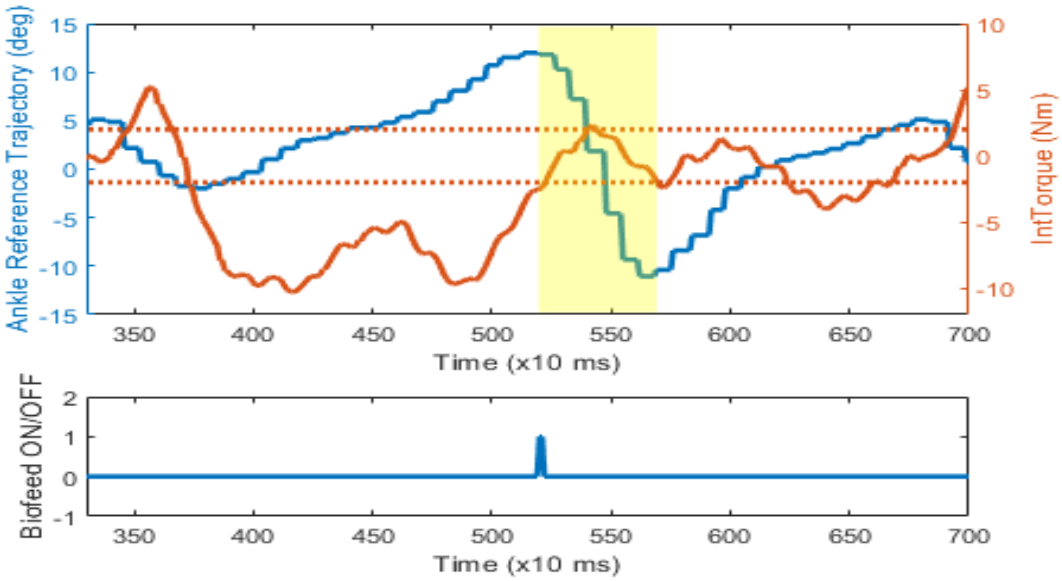


Figure 6.4 – State of the sonorous stimulus (on=1/off=0), Biofeed, the SmartOs-ankle orthosis reference trajectory (deg), Ankle Reference Trajectory, and the interaction torque (Nm), IntTorque, during the joint motion biofeedback strategy with actuation phase 3. The sonorous stimulus is enabled when the interaction torque is below the baseline interaction torque (±2 Nm).

6.1.2 Therapist-oriented strategy

When it turns out that the user is applying a counterforce to the orthosis, the visual stimulus is enabled with red colour (Figure 6.5A). In the opposite case, when the user does not apply a force over the orthosis (the user is synchronized with the orthosis) or applies a force with the same direction of the orthosis's movement, the visual stimulus is enabled with green colour (Figure 6.5B). The light only appears during the actuation phase. Thus, the therapist should motivate and advice the patients, accordingly. The colours were chosen to be intuitive to the therapist, since the red colour indicates a low

user's performance and the green colour indicates a high user's performance. Also, the therapist can accurately identify the actuation phase because the light only appears during it.

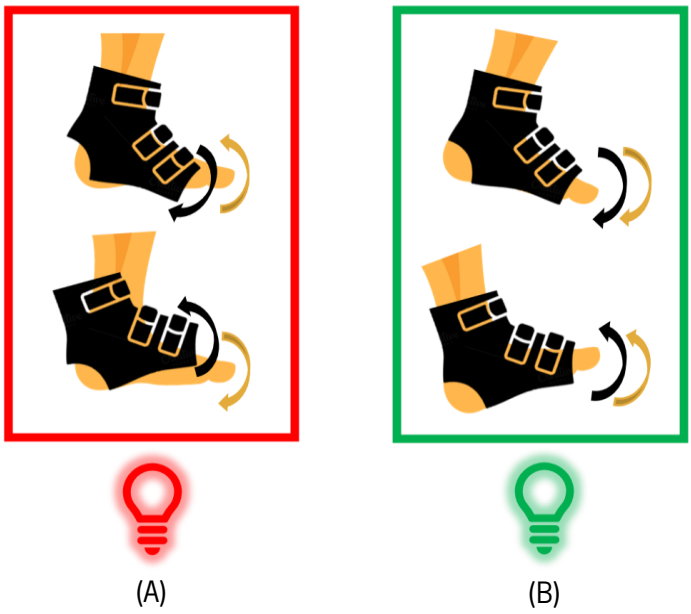


Figure 6.5 - Schematic of the joint motion therapist-oriented biofeedback strategy. User is (A) against and (B) according the orthosis's movement. The black and yellow arrows represent the orthosis's and user's movement, respectively.

6.1.3 Validation protocol

Participants

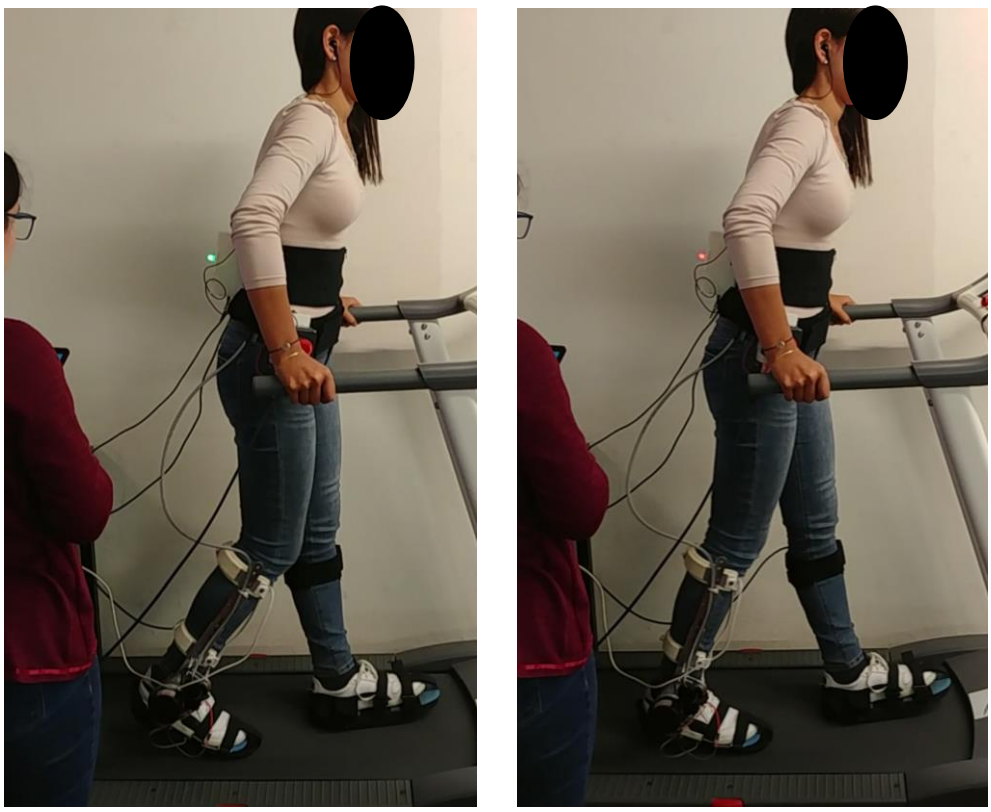
The six healthy participants, who were recruited for the validation protocol of the foot-floor contact biofeedback strategies, were recruited to perform the validation protocol of the joint motion biofeedback strategy.

Experimental Protocol

As the previous strategies, only one training session was performed. This training session was performed after the sessions of the foot-floor contact biofeedback strategies. This order was chosen since the users need to firstly learn when and how to perform the foot-floor contact and, then, the direction of movement along the gait cycle.

The training session of the experimental and control groups comprises the same procedures as mentioned in the previous biofeedback strategies (Chapter 5).

Figure 6.6 shows pictures of the participant 1 during the training with the joint motion biofeedback followed by the therapist (actuation phase 3).



(A) (B)

Figure 6.6 – Joint motion biofeedback training of the participant 1 followed by the therapist (actuation phase 3). (A) The sonorous stimulus is not enabled (green light) indicating that the participant is applying a plantar flexion force; (B) The sonorous stimulus is enabled (red light) indicating that the participant is applying a counterforce (dorsiflexion force).

Data Collection and Analysis

During this session, the interaction torque from the orthosis's embedded strain gauges and the reference trajectory were acquired. After the pre-training trials (procedure 1), the actuation phase is chosen to be used during the biofeedback training. Data collection was performed at 100 Hz. Note that no data were acquired during the familiarization procedure. The comments of the participants from the experimental group and the therapist were registered after the use of the biofeedback.

In order to validate the joint motion biofeedback strategy, it was calculated the user's average underperformance, as a percentage of the gait cycle's phase, for the actuation phase before, during and after the use of the BS. Also, this parameter was calculated for the remained gait cycle phases in order to study the influence of the biofeedback.

The average underperformance was calculated according the biofeedback strategy's principles. This is, the samples of the performed trials, that are in condition to enable the biofeedback, were identified: for the actuation phases 1 and 3, it corresponds to interaction torque's samples below -2 Nm; for the actuation phases 2 and 4, it corresponds to interaction torque's samples above 2 Nm. The

reference trajectory allows identification of the gait cycle's phases. The first and last three gait cycles of each trial were discarded for analysis.

Three paired one-side *t*-tests (0.05 level of significance) were performed: two for the experimental group and one for the control group.

For the **experimental group**, the first *t*-test was performed between the average underperformance of the actuation phase **before** and **during** the use of the biofeedback. The second *t*-test was performed between the average underperformance of the actuation phase **before** and **after** the use of the biofeedback. The first statistical analysis aims to evaluate if the average underperformance decreased significantly during the use of the BS. The null hypothesis is "there is no statistically significant differences between the average underperformance of the actuation phase before and during the use of the BS". The second statistical analysis aims to evaluate if the experimental group, during retention trial, was capable of autonomously replicate the learned gait pattern. The null hypothesis is "there is no statistically significant differences between the average underperformance of the actuation phase before and after the use of the BS".

For the **control group**, the *t*-test aims to evaluate if the significant decreased average underperformance (resulted from the first *t*-test of the experimental group) was caused by the BS. Firstly, the actuation phase of each participants of the control group was selected (gait phase with higher average underperformance during the first round of three trials). Then, the *t*-test was performed between the average underperformance of the actuation phase **before** and **during** the second round of three trials. The null hypothesis is "there is no statistically significant differences between the average underperformance of the actuation phase before and during the second round of three trials".

6.1.4 Results and Discussion

Table 6.1 presents the actuation phase of each participant.

Table 6.1 - Actuation phase of each participant during joint motion biofeedback training

	Actuation phase
Participant 1	3
Participant 2	3
Participant 3	3
Participant 4	2

By analysing Table 6.1, it can be concluded that phase 3 is the one where the participants felt more difficult to follow the orthosis's direction of movement.

Figures 6.7 show the average underperformance for each phase before, during and after the use of the BS for the participants 1, 2, 3 and 4, belonging to the experimental group.

Figures 6.8 show the average underperformance for each phase before, during and after the second round of three trials (only with the orthosis) for the participants 5 and 6, belonging to the control group.

Table 6.2 presents the comments of the participants after the use of the BS.

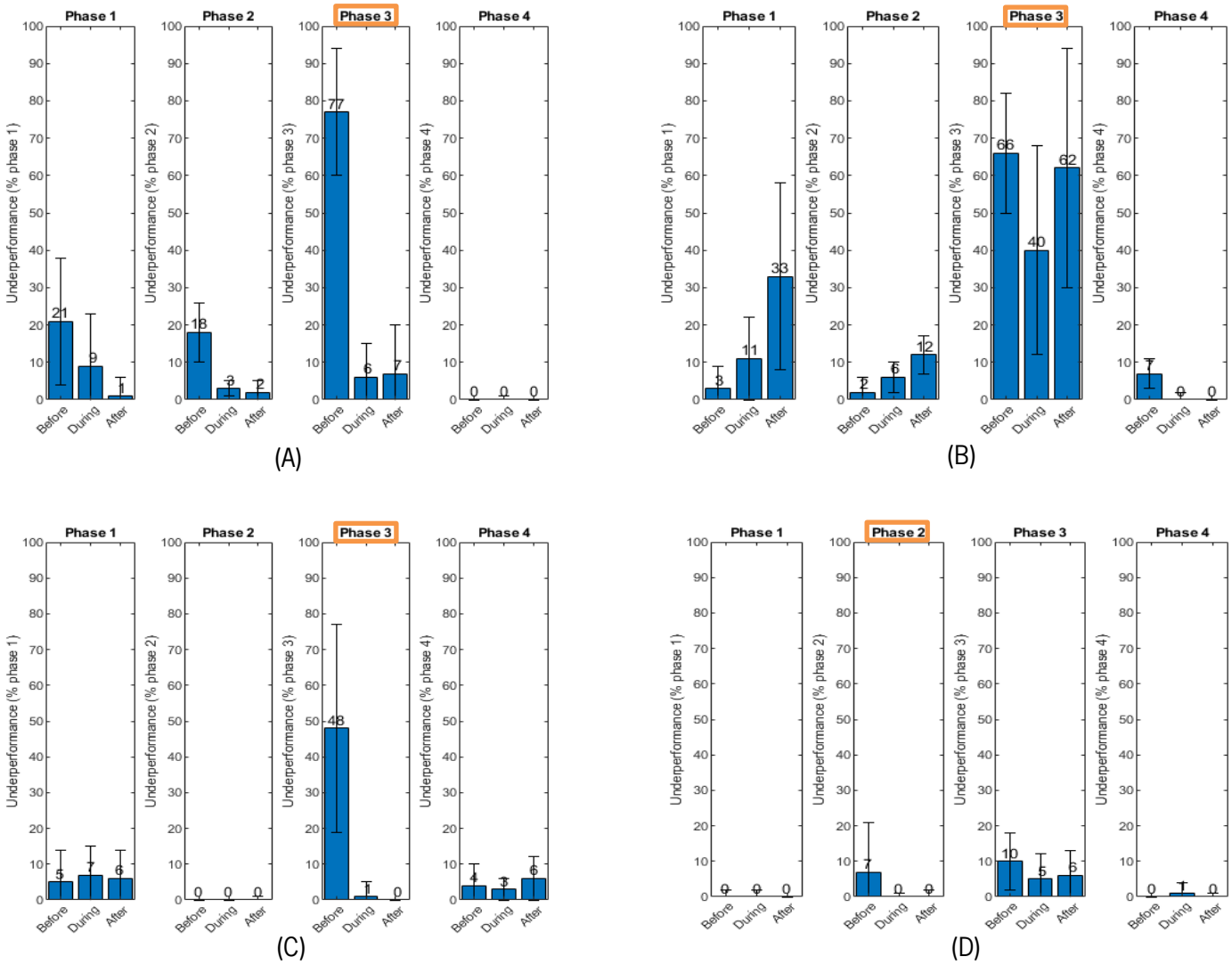


Figure 6.7 - Average underperformance (% of phases 1, 2, 3 and 4) before, during and after the joint motion biofeedback training of the participant (A) 1, (B) 2, (C) 3 and (D) 4, belonging to the experimental group. The actuation phase is evidenced in orange.

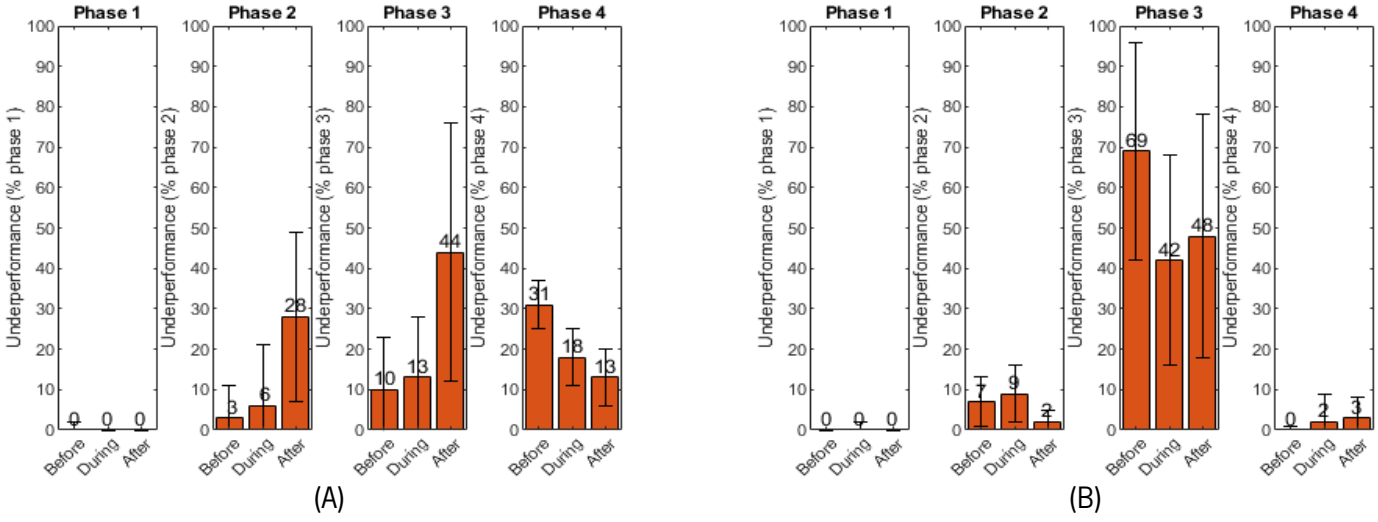


Figure 6.8 - Average underperformance (% of phases 1, 2, 3 and 4) before, during and after the second round of three trials only with the orthosis of the participants (A) 5 and (B) 6, belonging to the control group.

Table 6.2 - Participants' comments after the use of the joint motion biofeedback

Participant 1	Participant 2	Participant 3	Participant 4
• The sonorous stimulus is pleasant and allows multitasking (therapist's advices); • She felt that the orthosis no longer pushes her foot.	• The biofeedback strongly helps the users to be sensitive to the orthosis's movement; • She thinks that this strategy was efficient and effective in what concern to the synchronism between her and orthosis.	• It is motivating to know the performance in real-time through the biofeedback and this is an efficient strategy to rectify an incorrect behaviour; • He felt more active during the use of the orthosis with the biofeedback.	• This strategy motivates the users to use the orthosis; • This strategy can be used to evaluate quantitatively the gait ability of patients with gait injuries.

By analysing Figures 6.7, all the participants decreased the average underperformance of the actuation phase during the use of the BS. The participants 1, 2, 3 and 4 decreased in 71 %, 26 %, 47 % and 7 % the average underperformance during the use of the BS, respectively (as commented by the participants – Table 6.2). Moreover, the lower decrement observed in participant 4 (7 %) is equal to the average underperformance before the use of biofeedback, meaning that the biofeedback helped the participant 4 to achieve the 0 % of underperformance.

In the retention tests (Figure 6.7), the participant 2 was the only participant who increased the average underperformance after the use of the BS in comparison to the biofeedback training (22 %). It means that most of the participants learned the taught gait pattern during the use of the biofeedback and they were capable of autonomously replicate the pattern after 2 min of the end of the training period.

Relatively to the other phases (Figure 6.7), the participant 1 decreased the average underperformance of the phases 1 (12 %) and 2 (15 %). The participant 2 decreased 7 % in phase 4 but increased in phases 1 and 2. It reveals that the participant 2 needs to use, in the future, this strategy for other actuation phases. In this manner, it is not correct to think that improving the performance of one phase causes an improvement in the other phases. Consequently, it is important to apply this biofeedback strategy in each phase that the user needs. The participant 3 slightly varied his performance in the remained phases possibly due to the low underperformance registered before the use of the BS. Having in the count all the phases, the participant 4 is the participant who moves more synchronously with the orthosis according to the calculated average underperformance.

In general, the participants of the control group increased the average underperformance for all the phases, except for the actuation phase, during the execution of the second round of three trials (Figure 6.8).

Table 6.2 shows that the participant 1 commented that the sonorous stimulus is pleasant and allows to ear the therapist, proving the multitasking feature of the BS. The participant 2 mentioned that the joint motion biofeedback strategy helped her to be more sensitive to the orthosis's movement. The participant 3 mentioned that this strategy motivates him to use the orthosis, as mentioned by the participant 4. The participant 4 noted, also, that this strategy is useful to quantify his gait ability moving with the orthosis. Moreover, participant 1 felt the orthosis no longer pushed her foot, indicating that she is more synchronized with the orthosis, as mentioned by the participant 2 and 3. The participant 3 felt that he is more active using the orthosis.

The therapist commented that it is practically impossible to detect when the healthy user is moving or not in accordance with the orthosis's direction of movement without the biofeedback. Therefore, beyond the visual stimulus is easily understandable, it provides useful information about the user's performance that is, otherwise, unknown. Also, the activation of the visual stimulus only during the actuation phase helps to accurately identify this phase. Otherwise, the actuation phase is identified through visual inspection of the orthosis's movement that is not rigorous.

According to the strategies used by the healthy participants to improve their pattern, advised by the therapist, it was concluded that the low underperformance is caused by the lag between their movement and the orthosis's movement and their semi-passive behaviour (the subjects mostly apply their weight and did not moves actively, contracting their muscles).

Table 6.3 presents the *p*-values resulted from the *t*-tests between the average underperformance of the actuation phase before and during, and, then, before and after the use of the BS for the participants of the experimental group.

Table 6.3 - *P*-values of the *t*-tests between the average underperformance of the actuation phase (% of the actuation phase) before and during, and, then, before and after the use of the biofeedback for the participants of the experimental group

	Average underperformance (% actuation phase)		
	During use BS	Before use BS	After use BS
Participant 1	6	77	7
Participant 2	40	66	62
Participant 3	1	48	0
Participant 4	0	7	0
P-values	0.036		
		0.069	

The first result in Table 6.3 (*p*-value=0.036) shows that the average underperformance significantly decreased during the use of the BS. Therefore, these results reveal that the joint motion biofeedback strategy teaches effectively and efficiently the orthosis's users about the direction of movement during the actuation phase according to the orthosis's reference trajectory, improving the human-orthosis interaction. Although most of the participants decreased the average underperformance after the use of the BS in comparison to the biofeedback training, the second result in Table 6.3 (*p*-value=0.069) indicates that the participants need more biofeedback training to be able to significantly improve their gait pattern after the use of the biofeedback.

Table 6.4 presents the *p*-value of the *t*-test performed between the average underperformance of the actuation phase before and during the second round of three trials for the participants of the control group. The actuation phase of the participants of the control group were selected: participant 5 – actuation phase 4, participant 6 – actuation phase 3.

Table 6.4 - *P*-value of the *t*-test between the average underperformance of the actuation phase (% of the actuation phase) before and during the second round of three trials for the participants of the control group

	Average underperformance (% actuation phase)	
	Before use BS	During use BS
Participant 5	31	18
Participant 6	69	42
P-value	0.107	

The *p*-value from Table 6.4 shows that the control group did not significantly improved the average underperformance of the actuation phase after six trials of 1 min each only with the orthosis (*p*-value=0.107). It means that the first significant improvement of gait pattern observed in the experimental group (*p*-value=0.036) resulted from the BS.

In the end, there is a need to perform a new validation protocol with a large group of participants and a longer biofeedback training period, considering all phases to better investigate the effects of this biofeedback strategy.

6.2 User participation biofeedback strategy

The user participation biofeedback strategy aims to teach the user to adjust the magnitude of the force applied to the orthosis according to its healthy reference trajectory, improving the human-orthosis interaction. As mentioned before, the module of the interaction torque increases regarding the orthosis's

baseline interaction torque along with the increase of the force applied to the orthosis (Appendix I). Moreover, when there is a synchronization between the user and orthosis no interaction force is observed, that is, the user is activating his/her muscles according a healthy pattern. It is important to notice that when the user is passive, that is, only applies his/her weight to the orthosis, the interaction torque increases in relation to the orthosis's baseline interaction torque, which is not aimed (Appendix I).

6.2.1 User-oriented strategy

According to the interaction torque recorded during a pre-training trial (without the BS) along with x gait cycles, an interaction torque target interval, $IntTorque\_TargInt$, adjusted to the imminent user's gait performance, is calculated through Equation 6.1, where $IntTorque$ is the interaction torque (Nm) and i is the number of the gait cycle (from 1 to x).

$$IntTorque\_TargInt = \pm \frac{\frac{\sum_{i=1}^{x} \max\left(|IntTorque|\right)}{x}}{2} \tag{6.1}$$

In this strategy, a stimulus is enabled every time that the measured interaction torque exceeds the target interval. Therefore, when the users detect the stimulus, they need to control the force applied to the orthosis towards synchronization and, consequently, the stimulus stops. Before each training session, the interaction torque target interval should be updated to the recovery be gradually and, consequently, do not overwhelm the patient. Thus, the interaction torque target interval should decrease along with the therapy (the $IntTorque\_TargInt$ should be calculated before each session) until the orthosis's baseline interaction torque range (± 2 Nm) (Appendix I). In this case, the user actively follows the healthy orthosis's movement and, consequently, the recovery is completed.

The stimulus can be activated during one or more of the indicated actuation phases presented in Figure 6.3 (phases 1, 2, 3 and 4). In this manner, the pre-training trials should be analysed in order to conclude about the phases in which the user has the lowest performance. If the user has a considerable low performance in more than one phase, it is more effective to recovery one phase at a time to not overwhelm the patient.

In this strategy, the vibrotactile shank band is the chosen stimulator since the vibrotactile stimulus can stimulate the principal active muscles during gait for ankle motion [38] and, consequently, help the patient to actively control them. The soleus muscle is responsible for the plantar flexion, that should occur during the phases 1 and 3. The tibialis anterior is charged for the dorsiflexion that should occur during

the phases 2 and 4 [7]. Therefore, if the interaction torque is higher than the $IntTorque\_TargInt$ during the phases 2 and 3, the ERM motor positioned in the front of the shank is enabled at 200 Hz and 1.8 G. If the interaction torque is lower than the -$IntTorque\_TargInt$ during the phases 1 and 4, the ERM motor positioned in the back of the shank is enabled at 200 Hz and 1.8 G. As reported in the chapter 2, this frequency was successfully used to enable vibrotactile motors placed on the shank of post-stroke patients [22].

Figure 6.9 shows a schematic of the user participation user-oriented biofeedback strategy.

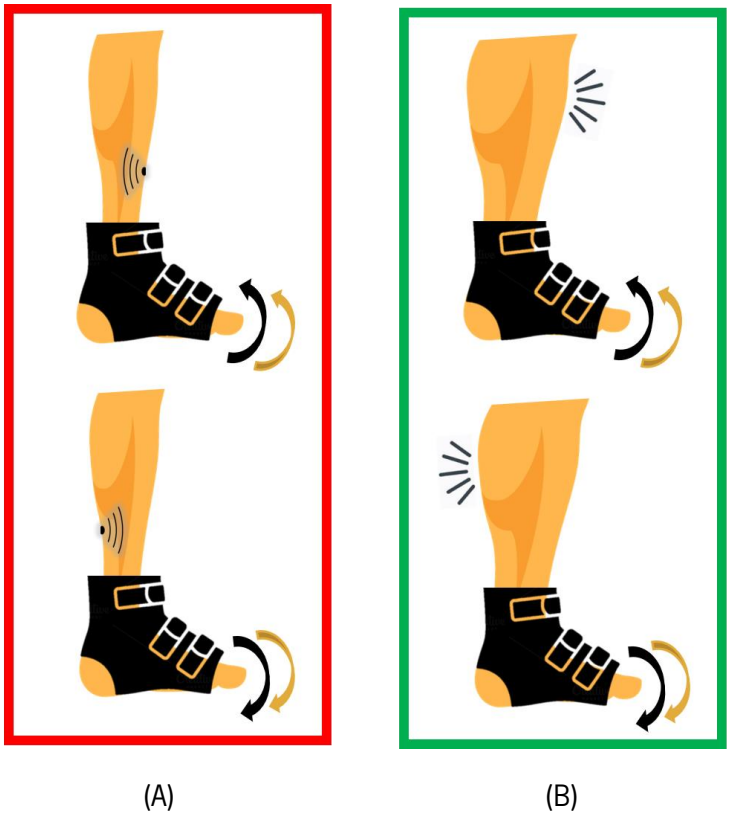


Figure 6.9 - Schematic of the user participation user-oriented biofeedback strategy. User moves (A) passively and (B) actively according the orthosis's movement. The black and yellow arrows represent the orthosis's and user's movement.

In general, during user participation biofeedback, the users should pay attention to the orthosis's movement and try to actively move in accordance. When the users perceive the vibrotactile stimulus, they should control their muscular force in order to follow the orthosis's angular velocity. As can be perceived, the users only need to distinguish the on and off state of the vibrotactile stimulus, which turns the BS easily understandable, following a user-centered design.

The on/off state of the vibrotactile stimulus is transferred from the LLOS to the CCU to be analysed at the end of the therapy in order to validate the correct functioning of the BS. Figure 6.10 shows the state of the vibrotactile stimulus during a trial running the user participation biofeedback strategy with actuation on phase 4 and $IntTorque\_TargInt$ equal to ±3 Nm.

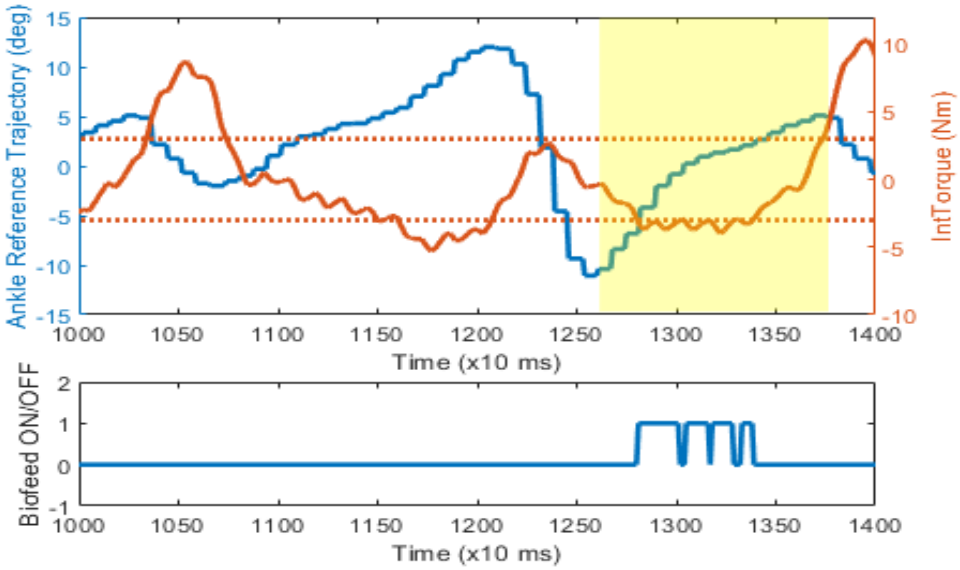


Figure 6.10 - State of the vibrotactile stimulus (on=1/off=0), Biofeed, the SmartOs-ankle orthosis reference trajectory (deg), Ankle Reference Trajectory, and the interaction torque (Nm), IntTorque, during the user participation biofeedback strategy with actuation phase 4. The vibrotactile stimulus is enabled when the interaction torque is below the target interval (±3 Nm).

6.2.2 Therapist-oriented strategy

When it turns out that the users are applying a force to the orthosis (which is not a counterforce), the visual stimulus is enabled with red colour (Figure 6.11A). On the other hand, when the users do not apply a force to the orthosis, indicating that they are actively following the orthosis's reference trajectory (considering the defined target interval), the visual stimulus is enabled with green colour (Figure 6.11B). The light only appears during the actuation phase. Thus, the therapist should motivate and advice the patients, accordingly. The colours were chosen to be intuitive to the therapist, since the red colour indicates a under desired user's performance and the green colour indicates an adequate user's performance. Moreover, the therapist can accurately identify the actuation phase.

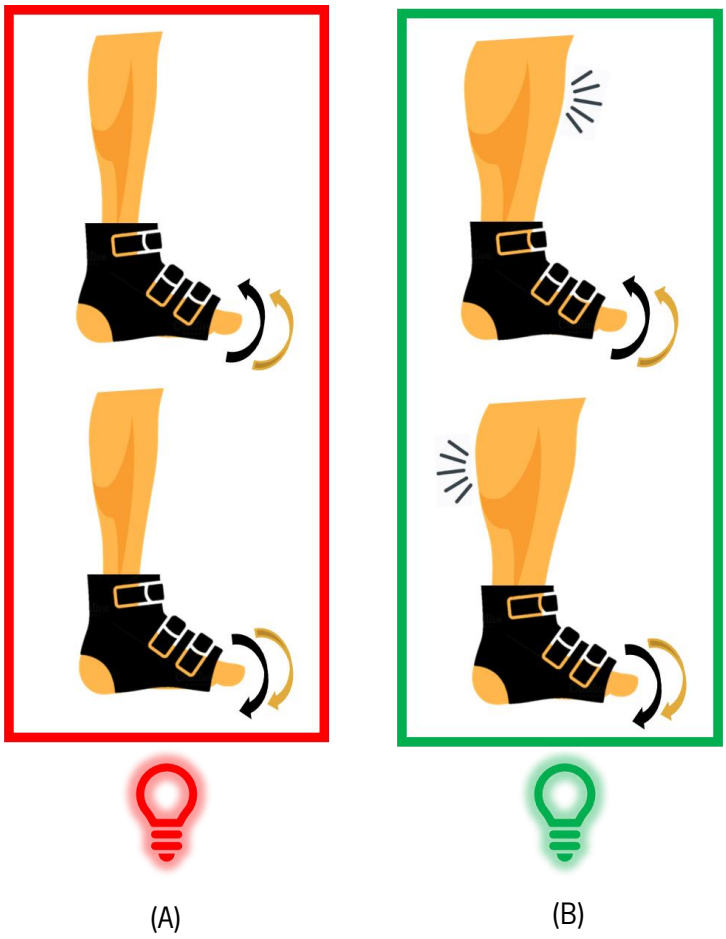


Figure 6.11 - Schematic of the user participation therapist-oriented biofeedback strategy. User moves (A) passively and (B) actively according the orthosis's movement. The black and yellow arrows represent the orthosis's and user's movement.

6.2.3 Validation protocol

Participants

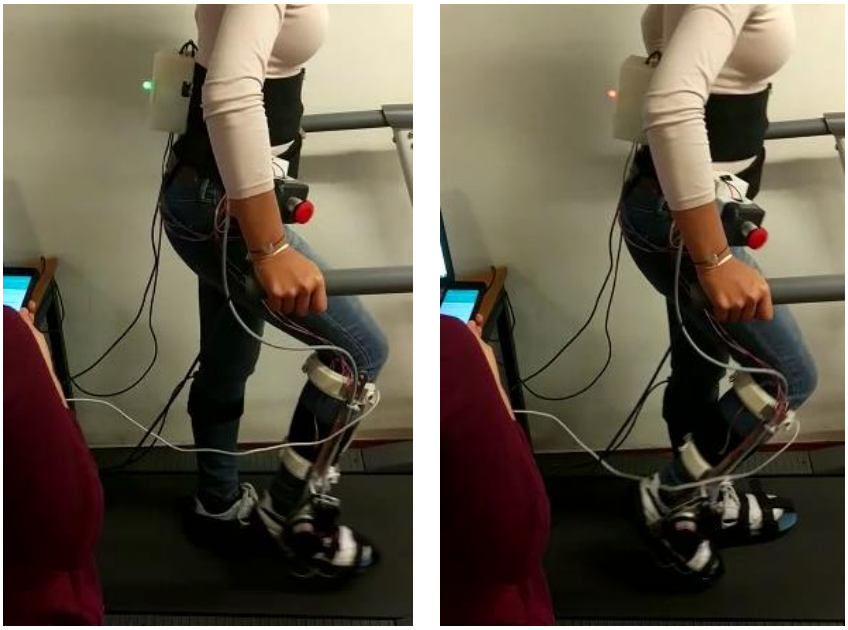
The six healthy participants, who were recruited for the validation protocol of the foot-floor contact and joint motion biofeedback strategies, were recruited to perform the validation protocol of the user participation biofeedback strategy.

Experimental Protocol

As the previous strategies, only one training session was performed. This training session was performed after the session of the joint motion biofeedback strategy. This order was chosen because the users need to learn, firstly, the direction of movement along the gait cycle and, then the adjustment of the muscular strength since the efficacy of one strategy may depend on the efficacy of the previous strategy.

The training session of the experimental and control groups comprises the same procedures as mentioned in the chapter 5 biofeedback strategies.

Figure 6.12 shows pictures of the participant 1 during the training with the user participation biofeedback followed by the therapist (actuation phase 4 and $IntTorque\_TargInt$ ±3 Nm).



(A) (B)

Figure 6.12 – User participation biofeedback training of the participant 1followed by the therapist (actuation phase 4 and $IntTorque\_TargInt$ ± 3 Nm). (A) The vibrotactile stimulus from shank is not enabled (green light) indicating that the participant is applying a dorsiflexion force in accordance with the orthosis's movement (interaction torque is above -3 Nm); (B) The vibrotactile stimulus from shank is enabled (red light) indicating that the participant is applying a dorsiflexion force that is not in accordance with the orthosis's movement (interaction torque is below -3 Nm).

Data Collection and Analysis

During this session, the interaction torque from the orthosis's embedded strain gauges and the reference trajectory were collected. After the pre-training trials (procedure 1), the actuation phase is chosen, and the interaction torque target interval is calculated to be used during the biofeedback training. Data collection was performed at 100 Hz. Note that no data were acquired during the familiarization procedure. The comments of the participants from the experimental group and the therapist were registered after the use of each biofeedback strategy.

The user's average underperformance was calculated, as a percentage of the gait cycle's phase, for the actuation phase before, during and after the use of the BS, to validate the user participation biofeedback strategy. Also, this parameter was calculated for the remained gait cycle phases in order to study the influence of the biofeedback.

The average underperformance was calculated according to the biofeedback strategy's principles. This is, the samples of the performed trials, that are in condition to enable the biofeedback, were identified: for the actuation phases 1 and 3, it corresponds to interaction torque's samples above the $IntTorque\_TargInt$; for the actuation phases 2 and 4, it corresponds to interaction torque's samples below the $IntTorque\_TargInt$. The first and last three gait cycles of each trial were discarded for analysis.

Four paired one-side *t*-test (0.05 level of significance) were performed: two for the experimental group and the remaining two for the control group.

For **experimental group**, the first *t*-test was performed between the average underperformance of the actuation phase **before** and **during** the use of the biofeedback. The second *t*-test was performed between the average underperformance of the actuation phase **before** and **after** the use of the biofeedback. The first statistical analysis aims to evaluate if the average underperformance decreased significantly during the use of the BS. The null hypothesis is "there is no statistically significant differences between the average underperformance of the actuation phase before and during the use of the BS". The second statistical analysis aims to evaluate if the experimental group, during retention trial, was capable of autonomously replicate the learned gait pattern. The null hypothesis is "there is no statistically significant differences between the average underperformance of the actuation phase before and after the use of the BS".

For **control group**, the *t*-tests aim to evaluate if the significant decreased average underperformance (resulted from the *t*-tests of the experimental group) was caused by the BS. Firstly, the actuation phase of each participant of the control group was selected (gait phase with higher average underperformance during the first round of three trials) and the $IntTorque\_TargInt$ was calculated (through interaction torque acquired during the first round of three trials). Then, the first *t*-test was performed between the average underperformance of the actuation phase **before** and **during** the second round of three trials. The null hypothesis is "there is no statistically significant differences between the average underperformance of the actuation phase before and during the second round of three trials". The second *t*-test was performed between the average underperformance of the actuation phase **before** and **after** the second round of three trials. The null hypothesis is "there is no statistically significant differences between the average underperformance of the actuation phase before and after the second round of three trials".

In the end of the session, the participants of the experimental group were asked to answer the questionnaire presented in the section 6.2.4 to evaluate their opinion about the usability of the developed BS, considering all the trained biofeedback strategies (paretic and non-paretic foot-floor contact, joint

motion and user participation biofeedback strategies). This questionnaire is based on the System Usability Scale (Digital Equipment Corporation, UK) that is a simple questionnaire that gives a global view of the subjective assessment of a system's usability [39].

6.2.4 Results and Discussion

Table 6.5 presents the actuation phase and the $IntTorque\_TargInt$ of each participant.

Table 6.5 - Actuation phase and $IntTorque\_TargInt$ (Nm) of each participant during user participation biofeedback training

	Actuation phase	$IntTorque\_TargInt$ (Nm)
Participant 1	4	±3
Participant 2	1	±4
Participant 3	2	±5
Participant 4	1	±4

Analysing Table 6.5, it can be concluded that there is not a prevalence of an actuation phase and the $IntTorque\_TargInt$ is close to the baseline interaction torque, as expected in healthy participants.

Figure 6.13 shows the average underperformance for each phase before, during and after the use of the BS for the participants 1, 2, 3 and 4, respectively, belonging to the experimental group.

Figure 6.14 show the average underperformance for each phase before, during and after the second round of three trials (only with the orthosis) for the participants 5 and 6, respectively, belonging to the control group.

Table 6.6 presents the comments of the participants after the use of the BS.

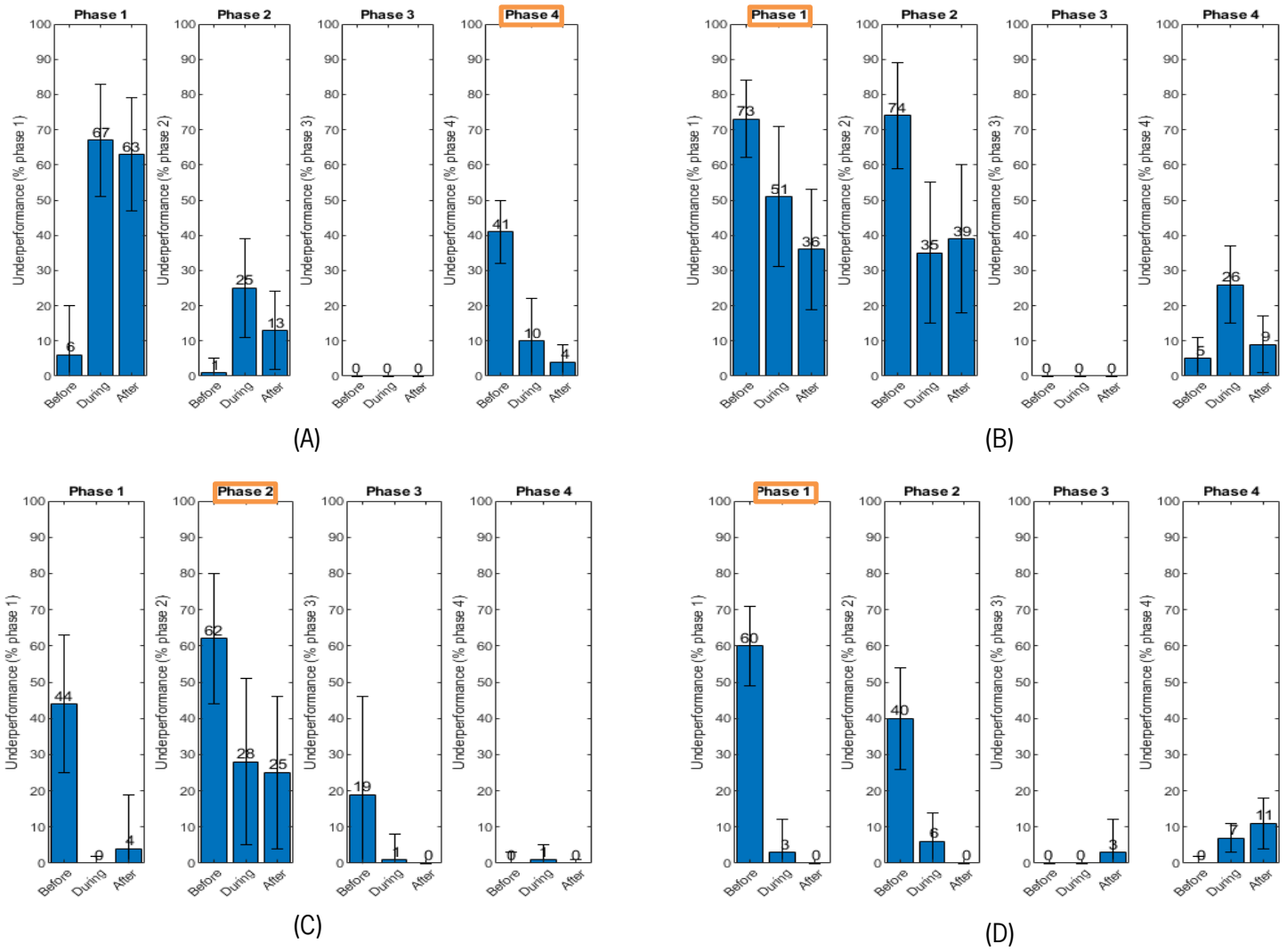


Figure 6.13 - Average underperformance (% of phases 1, 2, 3 and 4) before, during and after the user participation biofeedback training of participant (A) 1, (B) 2, (C) 3 and (D) 4, belonging to the experimental group. The actuation phase is evidenced in orange.

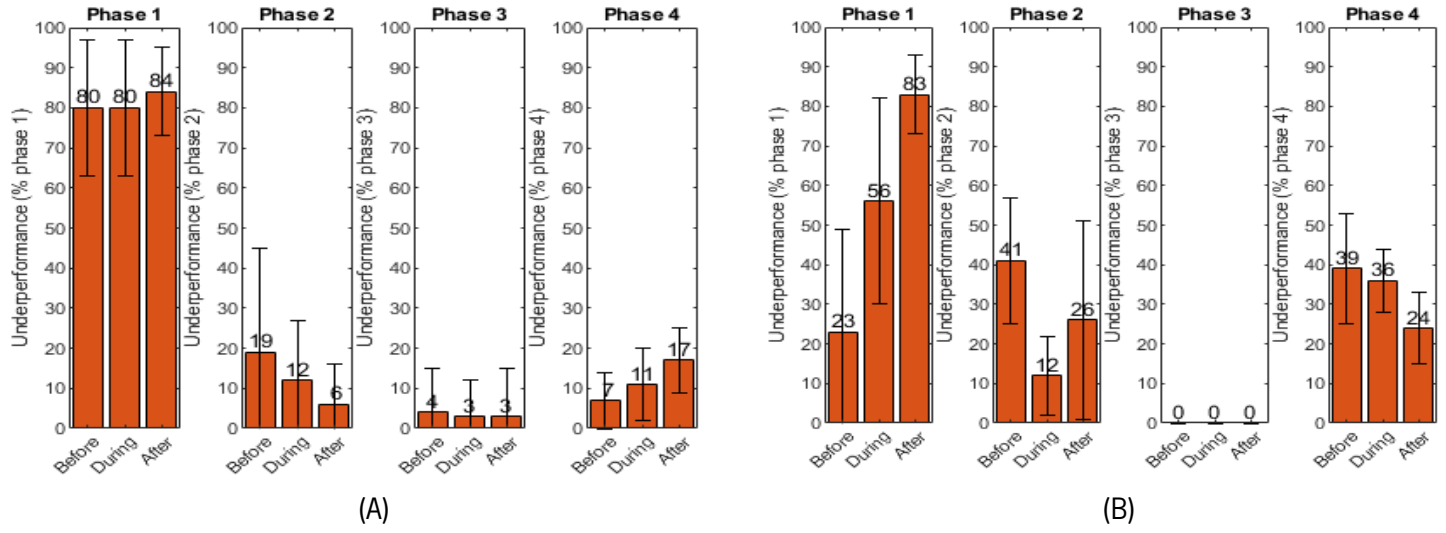


Figure 6.14 - Average underperformance (% of phases 1, 2, 3 and 4) before, during and after the second round of three trials only with the orthosis of participant (A) 5 and (B) 6, belonging to the control group.

Table 6.6 - Participants' comments after the use of the user participation biofeedback

Participant 1	Participant 2	Participant 3	Participant 4
• The intensity of the stimulus should increase; • She has more difficulty to improve her performance in comparison with the previous strategy; • She is motivated to use the biofeedback in other phases.	• It is difficult to pay attention to two haptic stimuli (vibrotactile cues and orthosis's movement) at the same time; • She is motivated to perform a longer biofeedback training.	• It is effective and ergonomic applying the stimulus on the trained limb, but the intensity should increase; • He felt that needs a longer training to achieve the best result.	• He is motivated to use the orthosis with the biofeedback; • The intensity of the stimulus should increase; • He felt that he is more synchronous with the orthosis.

As can be observed through Figures 6.13, all the participants decreased the average underperformance of the actuation phase during the use of the BS. In fact, the participants 1, 2, 3 and 4 decreased 31 %, 22 %, 34 % and 57 % of the average underperformance during the use of the BS, respectively (as commented by the participants – Table 6.6).

Relatively to the retention tests (Figures 6.13), all the participants decreased the average underperformance.

By analysing the user's performance in the other phases (Figure 6.13), the participant 1 increased the average underperformance in the phases 1 and 2, and the same happened to the participant 2 in phase 4. Findings indicate that improving the performance of one phase may not enhance the other phases. Consequently, it is important to apply this biofeedback strategy in each phase that the user needs. On the other hand, the participant 2 and 3 strongly decreased the average underperformance in the phase 2 (39 %) and phase 1 (44 %, achieving 0), respectively. Considering all phases, the participant 4 achieved the lowest average underperformance.

Through Table 6.6, the participant 1 commented that the intensity of the stimulus should increase to be easily perceived, as mentioned by the participant 3 and 4. The participant 2 felt difficulty paying attention to two haptic stimuli at the same time (orthosis's autonomous movement and vibrotactile stimulus). Thus, there is a need to improve the stimulus, increasing its intensity or changing to a sonorous one. The participant 1 demonstrated motivation to use the orthosis with the BS, as mentioned by the participants 2 and 4. Despite the increased underperformance achieved, the participants 1, 3 and 4 felt that this strategy has a higher level of difficulty in comparison with the joint motion strategy. This is expected once the participants should perform a longer training with the joint motion strategy (achieving

a closer to 0 % average underperformance in all the phases) before training with the user participation biofeedback strategy.

The therapist noted that her commentaries about the previous strategy are equally verified in this strategy.

Moreover, according to the strategies used by the healthy participants to improve their pattern, advised by therapist, it was concluded that the low underperformance is caused, in some cases, by their passive behaviour and, in other cases, by their extremely active behaviour in comparison with the orthosis's movement (that is, the participants needed to slower their movement), which is not expected with post-stroke patients.

Table 6.7 presents the *p*-values resulted from the *t*-tests between the average underperformance of the actuation phase before and during, and, the, before and after the use of the BS for the participants of the experimental group.

Table 6.7 - *P*-values of the *t*-tests between the average underperformance of the actuation phase (% of the actuation phase) before and during, and, then, before and after the use of the biofeedback for the participants of the experimental group

	Average underperformance (% actuation phase)		
	During use BS	Before use BS	After use BS
Participant 1	10	41	4
Participant 2	51	73	36
Participant 3	28	62	25
Participant 4	3	60	0
P-values	0.008		
		0.002	

The first result in Table 6.7 (*p*-value=0.008) shows that the average underperformance significantly decreased between before and during the use of the BS. So, it can be concluded that the user participation biofeedback strategy is capable to teach, effectively and efficiently, the users to adjust their muscular strength during the actuation phase, improving the human-orthosis interaction. Although, as mentioned by the participants 2 and 3 (Table 6.6), a longer biofeedback training is needed to achieve better results (< 51 % and < 28%, respectively) (Figures 6.18 and 6.19). The second result in Table 6.7 (*p*-value=0.002) shows that the participants were able to significantly improve their gait pattern after the use of the biofeedback. It means that the participants were able to autonomously replicate the pattern after 2 min of the end of the training period.

Table 6.8 presents the *p*-values resulted from the *t*-tests between the average underperformance of the actuation phase before and during, and, then, before and after the second round of three trials for the participants of the control group. The actuation phase of the participants of the control group were selected: participant 5 – actuation phase 4, participant 6 – actuation phase 3. Also, the $IntTorque\_TargInt$ was calculated: participant 5 - ±4 Nm, participant 6 - ±6 Nm.

Table 6.8 - *P*-values of the *t*-tests between the average underperformance of the actuation phase (% of the actuation phase) before and during, and, then, before and after the second round of three trials for the participants of the control group

	Average underperformance (% actuation phase)		
	During use BS	Before use BS	After use BS
Participant 5	80	80	84
Participant 6	12	41	26
P-values	0.250		
		0.333	

The *p*-values from Table 6.8 show that the control group did not significantly improve the average underperformance of the actuation phase after six trials (*p*-value=250) of 1 min only with the orthosis and neither after seven trials (*p*-value=0.333), respectively. It means that the significant improvements achieved in the experimental group may result from the biofeedback.

In the end, there is a need to perform a new validation protocol with a large group of participants and a longer biofeedback training period, considering all phases to better investigate the effects of this biofeedback strategy.

Figure 6.15 presents the questionnaire answered by the participants after the use of the BS.

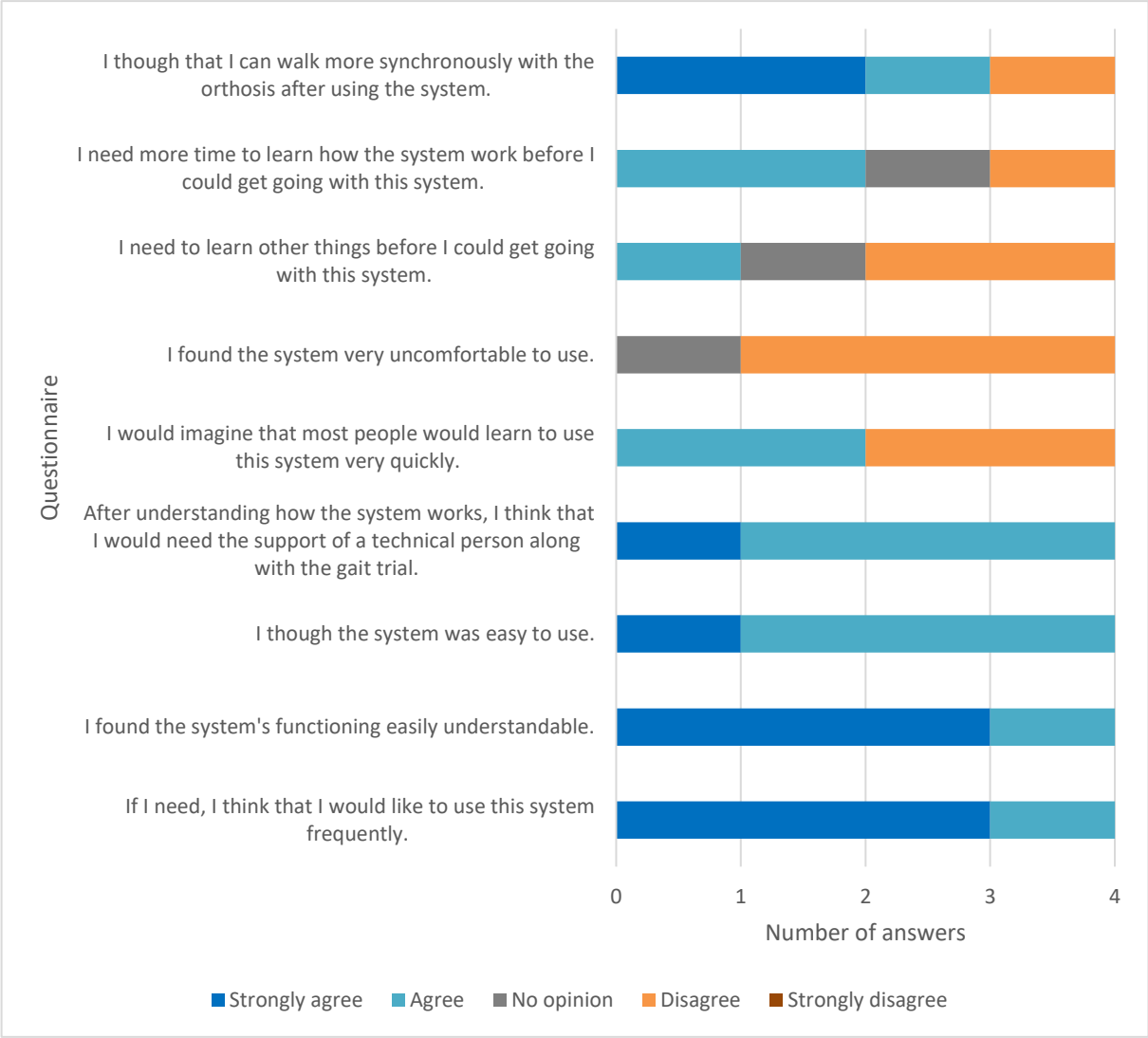


Figure 6.13 - User's appreciation questionnaire about the global BS.

According to the questionnaire's answers, most of the participants reported that they can walk more synchronously with the orthosis after using the BS; the system is not uncomfortable to use; after understanding how the system works, they would need the support of a technical person along with the gait trial; the system was easy to use; the system's functioning is easily understandable; if they need, they would like to use this system frequently. These results prove the high acceptability and efficacy of the developed BS.

On the other hand, there is no consensus relatively: "I need more time to learn how the system work before I could get going with this system", "I need to learn other things before I could get going with this system", "I would imagine that most people would learn to use this system very quickly". These findings appoint that a longer training with a large group of participants is needed.

6.3 Conclusions

The results from the joint motion and user participation biofeedback strategies revealed that these strategies can teach the orthosis's users, effectively and efficiently, about the direction of movement and the needed muscular strength during the actuation phase, respectively. The results from the *t*-tests showed that these strategies significantly improved the user's underperformance, improving the human-orthosis interaction. Moreover, the results from the control group indicated that the achieved significant results are truly caused by the biofeedback. In the case of the user participation biofeedback strategy, the results from the retention tests indicated that the participants were capable of autonomously replicate the learned pattern after 2 min of the end of the training.

The results from the questionnaire prove the high acceptability and efficacy of the developed BS.

In the end, there is a need to perform a new validation protocol with a large group of participants and a longer biofeedback training period, considering all phases to better investigate the effects of the biofeedback strategies.

7. CONCLUSIONS

Stroke has a strong incidence worldwide, and gait disabilities are common effects which limit the survivor's daily life. However, the survivors may regain their motor independence through rehabilitation, including robotic rehabilitation with robotic assistive devices, like active orthoses. The BS can be used as a complementary tool in orthotic gait rehabilitation, accelerating and increasing the effectiveness of the recovery, through the improvement of the human-orthosis interaction.

In this sense, this dissertation developed an economic, wearable, stand-alone and modular BS to be integrated into the SmartOs-ankle orthosis, based on a user-centered design, to teach the user to actively follow the orthosis's healthy reference trajectory.

The state of the art of the BSs currently developed for post-stroke gait rehabilitation reveal that there is a lack of BSs to be used in the field of orthotic rehabilitation and no wearable solution is available. In the non-orthotic rehabilitation field, there is prevalence to use ERM motors, attached to the user's body, as stimulators and FSRs as sensors. However, the sonorous, visual, and electrotactile biofeedback modes showed, also, positive effects in post-stroke motor recovery. Under the need of more than one biofeedback, there is evidence to prefer the combination of different biofeedback modes to reduce the user's cognitive load. Moreover, it was observed that all the developed visual BSs are non-wearable solutions.

Biofeedback follows user- and therapist-oriented strategies. Four user-oriented strategies were developed to promote a gradual improvement of the human-orthosis interaction, reducing the cognitive effort. These strategies aim to teach the user: (i) firstly, when and how to perform the paretic and, then, the non-paretic foot-floor contact; (ii) secondly, the direction of ankle rotation along the gait cycle; (iii) lastly, the necessary muscular strength along the gait cycle. Each user-oriented strategy involves a therapist-oriented strategy that successfully allowed the therapist to participate in the therapy.

The developed BS provides sensory, sonorous and visual stimulation through vibrotactile motors, headphones, and an RGB LED, respectively. Furthermore, it includes a STM32F4-Discovery board to manage the activation of these stimuli in real-time. The BS may operate in two operating modes: as a stand-alone, including a power supply and an external communication with the SmartOs; or integrated into SmartOs. In both operating modes, the BS is wearable, allowing ambulatory use. User-oriented strategies use sensory and sonorous stimuli and the therapist-oriented strategies employ the visual stimulus. The vibrotactile motors are placed on the user's waist and shank through elastic bands. The

participants of the validation protocol classified the system as comfortable, easy to use, and it allows multitasking.

The foot-floor contact biofeedback strategies are based on the orthosis's reference trajectory and use the vibrotactile waistband. The joint motion and user participation biofeedback strategies are based on the reference trajectory and interaction torque. These strategies use the headphones and vibrotactile shank band, respectively. In general, the user-oriented strategies were considered easily understandable, involving a low cognitive effort (except in the foot-floor contact strategies), and the stimuli were easily perceived (except in the user participation strategy). Regarding therapist-oriented strategies, visual stimulus was considered easily understandable, intuitive and allows the therapist to participate effectively in the therapy during the use of the BS.

The results from the foot-floor contact biofeedback strategies were not successful once most of the participants did not learn when to perform the paretic foot-floor contact according to the orthosis's movement and, also, they did not improve the symmetry between legs. Thus, there is a need to develop a more effective strategy to define the user's reaction time or to adjust the strategies to be based on the user's performance.

Findings from the joint motion and user participation biofeedback strategies revealed that these strategies can teach the orthosis's users, effectively and efficiently, about the direction of movement and the needed muscular strength during the actuation phase. However, before the clinical validation, there is a need to perform a more robust validation with healthy participants.

The results from the questionnaire of the BS's usability revealed that the participants felt that they walk more synchronously with the orthosis after using the biofeedback, proving the efficacy of the user-oriented strategies. The questionnaire also revealed that the participants would like to use the BS more frequently, proving the high acceptability of the BS. Lastly, it was reported the need for a technical person, proving the usefulness of the therapist-oriented strategies.

The presented work allows to answer the RQs appointed in Chapter 1:

- RQ1: How have the state-of-art BSs been designed and applied to reinforce post-stroke gait rehabilitation?

  Chapter 2 answered this RQ. Only one BS was found to be used in the field of orthotic rehabilitation, and it is a visual no-wearable solution applied to improve user participation during the therapy. In the non-orthotic rehabilitation field, more BSs are developed with prevalence to use ERM motors, attached to the user's body, as stimulators and FSRs as sensors. However, the sonorous, visual, and electrotactile biofeedback modes are also used, demonstrating positive

effects in post-stroke motor recovery, being all the visual solutions non-wearable. These BSs are applied to improve gait symmetry and weight bearing.

- **RQ2**: How can the BSs contribute to gait rehabilitation assisted by AOs using the trajectory tracking control?

  Chapter 3 answered this RQ. The BSs can accelerate the recovery of patients, who perform gait rehabilitation assisted by AOs, through the improvement of the human-orthosis interaction. In detail, the BSs can teach the orthosis's users about when and how should be made the paretic and non-paretic foot-floor contact (increasing the gait symmetry) and how to actively follow orthosis's healthy pattern: the direction of movement and the necessary muscular strength along the gait cycle. On the other hand, the BSs allow the therapists to accurately follow the patients' performance so that they can, effectively, participate in the therapy.

- **RQ3**: Does the BS improve, efficiently, the human-orthosis interaction?

  Chapter 5 answered this RQ. The results from the joint motion and user participation biofeedback strategies revealed that these strategies can teach the orthosis's users, effectively and efficiently, about the direction of movement and the needed muscular strength during the actuation phase, through the improvement of the human-orthosis interaction. The participants of the experimental group significantly decreased the average underperformance (joint motion p-value=0.036; user participation p-value=0.008) and the results from the control group reveal that the significant decrease was caused by the use of the biofeedback (joint motion p-value=0.107; user participation p-value=0.250).

7.1 Future Work

The future work comprises the following research directions: (i) to improve the foot-floor contact biofeedback strategies (through a more effective strategy to define the user's reaction time; to adjust the strategies to be based on the user's performance; to teach separately when to perform and stop the foot-floor contact; aiming gait symmetry, to teach the heel-off in detriment of heel-strike); (ii) to validate the foot-floor contact biofeedback strategy with the SmartOs passive control; (iii) to improve the stimulus in the user participation biofeedback strategy (by increasing the intensity or by using the sonorous stimulus in detriment of the vibrotactile one); (iv) to perform a new validation protocol with a large group of participants who had no familiarity with the orthosis and applying a longer biofeedback training; (v) to

perform longer retention tests; (vi) to proceed to technical improvements (miniaturization, to convert the BS in a wireless device; to create an Android application to easily manage the BS) to improve ergonomics; (vii) clinical validation with post-stroke patients; (viii) expansion the application through other orthotic therapies and robotic devices and/or sport field; (ix) scientific and commercial dissemination through rehabilitation clinics, hospitals and/or healthcare enterprises.

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APPENDIX I – INTERACTION TORQUE BEHAVIOUR

Figure 0.1 shows the behaviour of the interaction torque when no external weight and an external weight of 1.5 kg (equivalent to the foot's weight of a person with a body mass of 100 kg [40]) are applied to the orthosis during trajectory tracking control at 1.0 km/h. The weight is a force towards the decrease of the orthosis's angle, which varies its contribution along with the reference trajectory. As can be seen, the weight increases the interaction torque without changing the pattern. Thus, when no external forces are applied to the orthosis, the resulted interaction torque (baseline interaction torque) can be explained by the orthosis's weight and inertia.

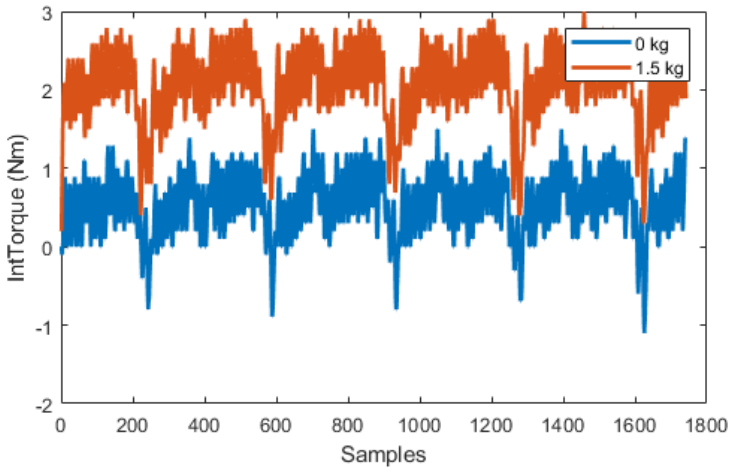

Figure 0.1 – Interaction torque (Nm), IntTorque, along five gait cycles in two conditions: the orthosis runs with no external weight and with 1.5 kg external weight. The SmartOs AFO runs the trajectory tracking control at 1.0 km/h.

Figure 0.2 shows the behaviour of the interaction torque when an external force is applied by the user's hand on the orthosis during trajectory tracking control at 1.0 km/h. Three rising forces were applied to the orthosis towards the decrease (Figure 0.2A) and increase (Figure 0.2B) of the orthosis's angle. By analysing Figure 0.2A, when a force is applied towards the angle's decrease, the interaction torque increases regarding the baseline. Moreover, through Figure 0.2B, when a force is applied towards the angle's increase, the interaction torque decreases in relation to the baseline. Also, through Figure 0.2, it can be concluded that the module of the interaction torque increases along with the increase of the applied force.

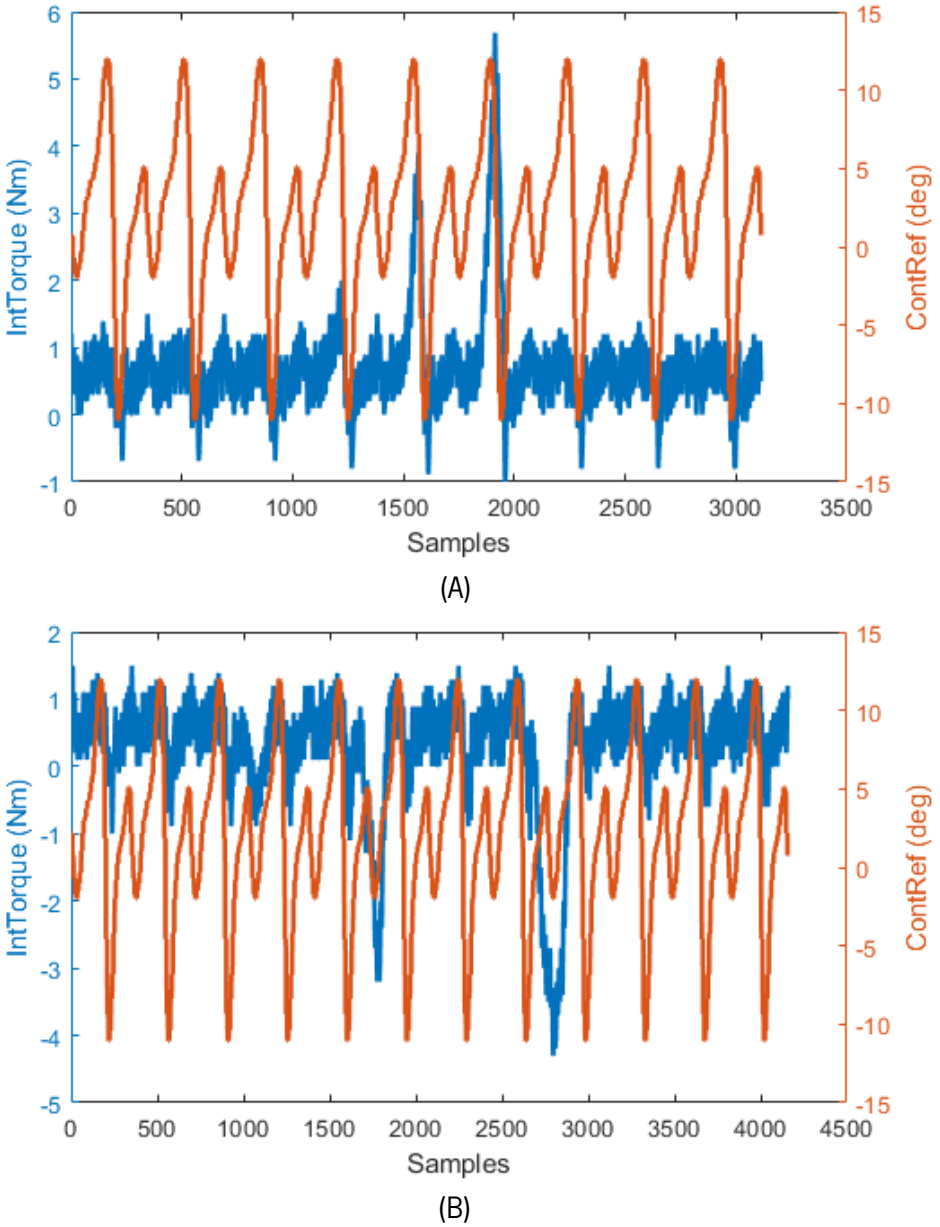

Figure 0.2 - Interaction torque (Nm), IntTorque, and reference trajectory (deg), ContRef, when three rising forces are, punctually, applied to the SmartOs AFO during trajectory tracking control at 1.0 km/h. The forces towards (A) the decrease and (B) the increase of the orthosis's angle.

APPENDIX II – THE NEED TO IMPROVE THE HUMAN-ORTHOSIS INTERACTION DURING TRAJECTORY TRACKING CONTROL

Figure 0.3 shows the interaction torque during 5 gait cycles for one healthy subject (age: 27 years, height: 1.62 m, body mass: 53 kg) who is familiarized with the orthosis. Also, it is presented the orthosis's baseline interaction torque. During both trials, the SmartOs-ankle orthosis assisted with the trajectory tracking control at 1.0 km/h. As can be seen, the user achieved higher and lower values of interaction torque in comparison to the baseline, indicating that the user is not synchronized with the orthosis. It proves the need to develop an effective strategy to improve the human-orthosis interaction torque. As can be seen, when the orthosis is moving from the maximum reference angle to the minimum reference angle, the interaction torque is negative, indicating that the user is applying a force against the reference trajectory. According to this, beyond the need to reduce the magnitude of the interaction torque, there is a need to change its signal.

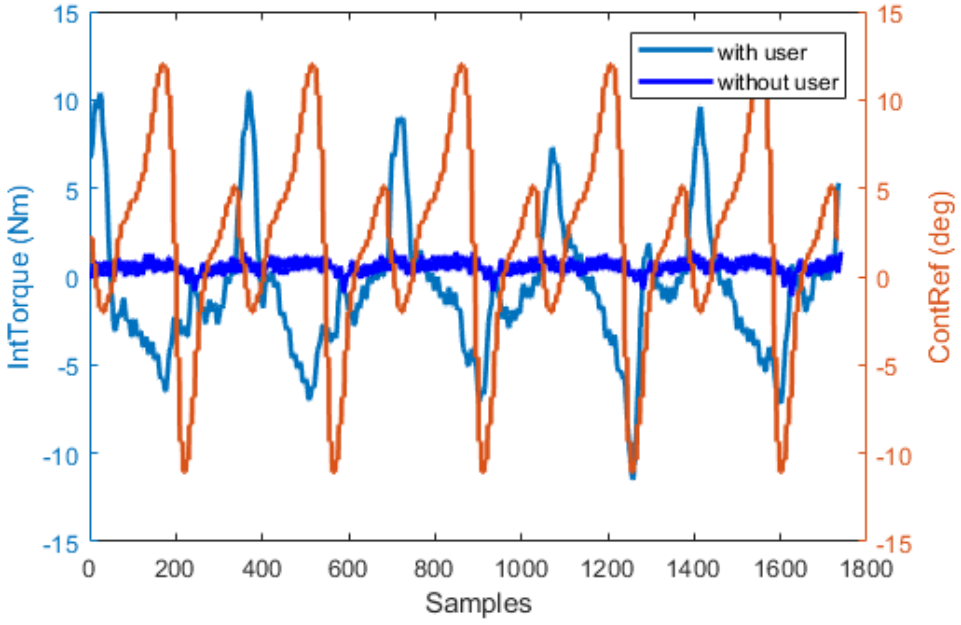

Figure 0.3 – Interaction torque (Nm), IntTorque, and reference trajectory (deg), ContRef, during SmartOs AFO trajectory tracking control at 1.0 km/h. It is presented the data when the orthosis runs alone and when a healthy subject tries to follow the orthosis's movement.

APPENDIX III – BS'S RELATED REACTION TIME

In order to define a system related reaction time to be used during the foot-floor contact biofeedback strategies, the following procedure was carried out. One healthy subject (age: 27 years, height: 1.62 m, body mass: 53 kg) performed three trials of 1 min with the paretic foot-floor contact biofeedback strategy (using no reaction time) and using the orthosis with the trajectory tracking control at 1.0 km/h. Before these trials, it was given time to the subject to be familiarized with the biofeedback. During this procedure, the participant was instructed to follow the orthosis movement with the BS's cues. It was acquired the data from the orthosis's embedded heel FSR and the reference trajectory.

To calculate the reaction time, firstly, the user's and orthosis's heel-strike events were identified through the heel FSR and the reference trajectory, respectively. Then, an average delay between the orthosis and the user's events was calculated, being that value used as the system related reaction time. The result was 470 ms.